

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products)
Liability Litigation,) MD 15-02641-PHX-DGC
)
_____))
)
Lisa Hyde and Mark Hyde, a married) Phoenix, Arizona
couple,) October 3, 2018
)
Plaintiffs,)
)
v.) CV 16-00893-PHX-DGC
)
C.R. Bard, Inc., a New Jersey)
corporation, and Bard Peripheral)
Vascular, an Arizona corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 12 - A.M. SESSION

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(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Good morning, Your Honor.

THE COURT: Counsel, last night, as I expect you saw, I sent out an order trying to indicate to you what my rulings were on the jury instructions. I want to give just a bit more explanation on the reason I concluded that the inherent characteristics defense should be included in the instructions.

I went back and reread the trial brief the plaintiffs had submitted and the arguments there. There were two cases cited in the plaintiffs trial brief: The *Godoy* case from Wisconsin Court of Appeals and the *Williams* case from the federal court in West Virginia. Is it West Virginia or Virginia? I think Southern District of West Virginia.

MS. HELM: West Virginia.

THE COURT: In the mesh litigation.

The *Godoy* case is the only case that the parties have cited that addresses this inherent characteristics defense. But *Godoy* was a pre-statute case. So it is not defining the defense that's in Section 3(d) of the statute. It's certainly

08:32:51 1 talking about the same case, but even as the *Williams* case
2 pointed out, *Godoy* is a common law decision, it's not an
3 interpretation of the statute.

4 And therefore, as I read *Godoy*, it does not define
08:33:08 5 the limits of what is an inherent characteristic for the
6 purposes of this statute. It certainly doesn't do so in a way
7 that allows me to conclude that the arguments Bard will be
8 making on this issue are unavailable as a matter of law: It
9 just doesn't purport to define the contours of what is or is
08:33:31 10 not an inherent characteristic under the statute.

11 The *Williams* case -- well, I ought to also add I know
12 the facts in *Godoy* are different. In fact, *Godoy* was talking
13 about an ingredient and defendants are not, in my view,
14 talking about an ingredient. But I don't think I can read
08:33:51 15 *Godoy* to say the statute therefore only applies to
16 ingredients.

17 The *Williams* case denied a motion for summary
18 judgment based on this defense, as I did in this case.

19 *Williams* did not talk about what instruction should
08:34:12 20 or should not be available at trial if there is a dispute of
21 fact among parties.

22 Now, granted, *Williams* did find that polypropylene
23 was not an essential characteristic of mesh and therefore the
24 defense was not available.

08:34:29 25 I don't know for sure what the judge would have done

08:34:32 1 with that at trial. He just denied the motion for summary
2 judgment, as I have done.

3 In this case it seems to me we have competing
4 evidence and arguments.

08:34:43 5 Defendants argue that the elements of the filter
6 design that are criticized by Dr. McMeeking are required
7 characteristics of their retrievable filter. Plaintiffs
8 disagree and argue that they're not required characteristics
9 and in fact there are alternative reasonable designs that Bard
08:35:02 10 could have used. There's clearly a dispute of fact on that
11 issue.

12 Defendants argue that the rates of failure of their
13 filter are within rates experienced by other filters and in
14 that respect, I suspect defendants will argue, are an inherent
08:35:21 15 characteristic of removable filters.

16 Plaintiffs disagree and presented evidence the rates
17 of failure exceed what is experienced by other filters and
18 therefore certainly not inherent characteristic of filters and
19 the rate could have been reduced.

08:35:40 20 So I think the evidence presented at trial creates a
21 debatable issue on whether or not it's an inherent
22 characteristic. And obviously there's this other undefined
23 term in the statute of what is -- I can't remember the exact
24 phrase. What is the common user of the filter and what is
08:36:03 25 their expectations. And the parties have disagreements on

08:36:07 1 that.

2 So my conclusion was, number one, I can't rule out as
3 a matter of law defendants' arguments based on any Wisconsin
4 case. There is a dispute of fact. Therefore, the question
08:36:23 5 was should I give the instruction?

6 Well, it's not in the jury instructions in Wisconsin,
7 but it is in a more authoritative place, which is the statute.
8 It's available under Wisconsin law. And if it's in the
9 statute, I don't think I can conclude that defendants are not
08:36:41 10 entitled to argue it at trial simply because there hasn't been
11 a Wisconsin model instruction adopted for it.

12 That's a bit more lengthy explanation of why I
13 concluded the instruction should be given.

14 I think the other rulings are sufficiently explained
08:36:58 15 in the order that I entered.

16 Plaintiffs' counsel, do you have matters you want to
17 talk about this morning?

18 MR. GOLDENBERG: I do, Your Honor. I want to make
19 sure even though the Court just explained this very well that
08:37:10 20 we do object to this and I'd just like to put -- just like to
21 make a quick record, if I could.

22 THE COURT: You can.

23 MR. GOLDENBERG: Would you prefer I stand or sit?

24 THE COURT: Whichever you prefer.

08:37:22 25 MR. GOLDENBERG: Okay. Your Honor, I just --

08:37:24 1 THE COURT: Pull the mic down -- pull the mic down a
2 little bit though.

3 MR. GOLDENBERG: Here we go.

4 First of all, we do believe that the *Godoy* case is
08:37:32 5 still controlling. We think that under the *Janusz* case, which
6 was the *Janusz versus Symmetry Med*, 256 F.Supp. 995 Wisconsin
7 217, that was a case that indicated that common law is not
8 superseded by inactive statutory scheme unless it's expressly
9 overturned.

08:37:57 10 There is nothing in *Godoy* that's expressly overturned
11 by that statute. And, really, the characteristic that was
12 talked about was an ingredient.

13 I know the Court has already said that. I'm
14 certainly not here to disrespect what you just said --

08:38:11 15 THE COURT: I know.

16 MR. GOLDENBERG: -- I'm just making a record.

17 THE COURT: That's fine.

18 MR. GOLDENBERG: I think both in *Williams* and *Godoy*
19 the ingredients, which were the white lead carbonate in one
08:38:20 20 and polypropylene in another, are not analogous to the facts
21 in this case. There's no ingredient that's been added to the
22 filter that makes it inherently -- an inherent concept that
23 somebody would understand.

24 I think this is kind of what I would call the knife
08:38:37 25 is inherently sharp defense, where we've got a statute that if

08:38:43 1 it's common knowledge that an average person would understand
2 that this is inherently dangerous, then this instruction
3 should be read.

4 That's how we read it.

08:38:53 5 And filter fracture is not an inherent characteristic
6 of the G2 or Eclipse filter. Retrievability is not an
7 inherent characteristic that would be recognized as an
8 ordinary consumer to cause fracture.

9 Filter fracture can be prevented or limited. I don't
08:39:09 10 think anybody disagrees with that. And Bard has actually
11 tried to do that in later models with caudal anchors and
12 penetrators.

13 So we believe that both based on the facts and the
14 law that this inherent characteristic defense under Wisconsin
08:39:25 15 statute 895.0473(a) should not be given.

16 THE COURT: Okay.

17 MR. GOLDENBERG: Thank you.

18 THE COURT: Do defendants want to say anything on
19 that issue?

08:39:37 20 MR. ROGERS: No, Your Honor.

21 THE COURT: Okay.

22 I think that's a reasonable argument. I just, for
23 the reasons I explained, am of the view I can't conclude that
24 *Godoy* is the -- sets the parameters of that statutory defense
08:39:51 25 because that's not what *Godoy* said it did. And I understand

08:39:55 1 what the *Janusz* case said about not overruling the common law,
2 which raises all kinds of questions in Wisconsin law. You are
3 on the record for and have absolutely preserved that
4 objection.

08:40:07 5 MR. GOLDENBERG: Thank you.

6 THE COURT: Are there other matters plaintiffs want
7 to raise before we start?

8 MR. O'CONNOR: I don't think we have anything.

9 THE COURT: How about from defendants?

08:40:19 10 MR. ROGERS: No, Your Honor.

11 THE COURT: Okay.

12 We'll get the jury in at 12 o'clock. I mean at 9
13 o'clock. We'll work our way through the evidence. When we
14 get to the close of evidence I'll call a sidebar to talk about
08:40:34 15 if there's a further Rule 50 motion or something that's to be
16 made, we can do that. And then the plan will be to do
17 instructions and go into closing arguments, but we'll also
18 talk about timing and what we do with the lunch hour, et
19 cetera.

08:40:47 20 MS. HELM: Your Honor, with the first witness, we are
21 going to use the pad, and may we just go ahead and move that
22 over?

23 THE COURT: Yeah. You mean hand --

24 MS. HELM: Write on the pad.

08:40:59 25 THE COURT: That's fine.

DIRECT EXAMINATION - MICHAEL RANDALL

08:41:03 1 Okay, we'll see you when the jury comes in.

2 (Recess taken from 8:41 to 8:58. Proceedings resumed in

3 open court with the jury present.)

4 THE COURT: Thank you, ladies and gentlemen. Please

09:02:34 5 be seated.

6 Good morning, everybody.

7 JURORS: Good morning.

8 THE COURT: We are going to continue with the defense

9 witness.

09:02:42 10 MS. HELM: Your Honor, at this time we call Mike

11 Randall.

12 THE COURTROOM DEPUTY: Mr. Randall, if you'll please

13 come forward, raise your right hand.

14 THE COURT: Were you here previously in trial,

09:02:51 15 Mr. Randall?

16 THE WITNESS: Yes.

17 THE COURT: So you're still under oath. You can come

18 straight back to the witness stand.

19 It's been a long three weeks. I should remember

09:03:05 20 that.

21 Go ahead, Ms. Helm.

22 MS. HELM: Thank you, Your Honor.

23 **MICHAEL RANDALL,**

24 recalled as a witness herein, after having been previously

25 sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION - MICHAEL RANDALL

D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Mr. Randall, would you please reintroduce yourself to the jury.

A Michael Randall. I'm a director of research and development for Bard.

Q And would you briefly tell the jury your educational background.

A I graduated from University of California, Irvine, with a degree in mechanical engineering, specializing in mechanical systems, and also hold an MBA from Thunderbird University.

Q And why did you decide to go to work in the field of medical devices?

A Well, originally I wanted to be interventional cardiologist, but when I graduated I was making some pretty good money and just had my first son so it just felt natural to stay because I still could help people out by creating things. So I decided to say in medical devices.

Q Is Bard the first medical device company you've worked for?

A No. Two previous companies. The first one was Baxter Healthcare and the second was Edwards Lifesciences. I worked there for a combined 11 years.

Q When did you join Bard?

A 2006.

DIRECT EXAMINATION - MICHAEL RANDALL

Q When you joined Bard in 2006, did you immediately start working on IVC filters?

A Not immediately.

Q What did you work on first?

A I was working on PTA, which is our balloon franchise.

Q And when you found out you were going to switch over to IVC filters, what was your reaction?

A I was actually happy. Because when you work on med devices, balloons, they're a device that goes in, comes out.

The IVC filter is an implantable device so they're more challenging. So you put your good engineers on the more challenging stuff. So it was kind of like a promotion to me.

Q Mr. Randall, do you hold any patents?

A Yes, I have several patents. I have patent on a vena cava filter, the Denali, some stent delivery systems, and also some PTFE vascular grafts.

Q And are there other people at Bard that you worked with who also have patents on IVC filters?

A Yes. Actually Rob Carr has patents, Andrzej Chandusko has patents. In fact, Andrzej has the most patents at BPV.

We have this inventor hall of fame and Andrzej is at the goal level. And there's only one person ahead of him, who's retired. Andrzej's going to be there soon. I think he has like over 70 patents or something.

Q I'm going to switch gears and talk a little bit about the

DIRECT EXAMINATION - MICHAEL RANDALL

09:05:50 1 dynamics of the inferior vena cava filter and the challenges
2 that presents from an engineering perspective.

3 As part of your work at Bard, have you personally
4 researched medical literature about the dynamics of the
09:06:04 5 inferior vena cava filt- -- inferior vena cava?

6 A Yes.

7 Q And what types of publications and literature have you
8 reviewed?

9 A Some peer reviewed articles. There's lot of articles on
09:06:16 10 respiratory effects on the vena cava, hydration and how that
11 affects the vena cava. Different journals like JVIR. There's
12 a lot of standards, too. Society of Interventional Radiology.
13 So there's a lot of articles out there that we've looked at
14 with people who study the cava and other literature on other
09:06:39 15 filters, too.

16 Q In addition to literature research, have you taken --
17 undertaken any other activities to understand the inferior
18 vena cava?

19 A Yes. Actually one of the cool things we did as a team is
09:06:55 20 myself, Andrzej, and probably three or four more engineers, we
21 rented an MRI facility. And we had to sign waivers from HR.
22 We told them, hey, we want to go image our own cavas. So we
23 went and we all jumped in the MRI and imaged our cava to try
24 to understand it better.

09:07:18 25 Q And when did you do that, approximately?

DIRECT EXAMINATION - MICHAEL RANDALL

09:07:23 1 A I'd say that was probably 2 -- either 2007, 2008. I'm not
2 sure.

3 Q Okay. Has your knowledge of the inferior vena cava grown
4 exponentially over the years since you started working on IVC
09:07:41 5 filters?

6 A Yes. I think every day you're learning something new.
7 Bard was the first in this space and what they knew then was
8 as much as you possibly could have known. Today, we just
9 continue to learn more and more. It's just how it goes.

09:07:59 10 Q And based on your knowledge and your work with IVC filters
11 since 2007, what about the inferior vena cava makes designing
12 an implantable device challenging?

13 A So the vena cava is really dynamic.

14 You have to deal with blood flow but it's not like
09:08:19 15 the arterial side. The cava's kind of a reservoir, so the
16 blood, it's kind of stagnant how it flows. But there's also
17 contraction that happens. So radially the cava will expand
18 and collapse. The cava will also stretch with breathing. You
19 know, you take a breath, your diaphragm goes down, your cava
09:08:43 20 goes down a little, you exhale, diaphragm goes up, cava will
21 kind of stretch, too. And then the shape of the cavas,
22 they're all different. And there's just a lot of things going
23 on. It's very challenging environment.

24 Q And in addition to the challenging environment of the vena
09:09:03 25 cava itself, what are some of the challenges in developing a

DIRECT EXAMINATION - MICHAEL RANDALL

09:09:08 1 long-term retrievable IVC filter?

2 A With -- with designing the long-term retrievable filter,
3 you've got competing attributes. You want to make it so it's
4 stable, doesn't move. But you also want to make it so it can
09:09:28 5 be retrieved. You also want to make it so it traps clot. But
6 you also don't want it to be thrombogenic. So that affects
7 how much of a scaffolding you put in place. If you put too
8 much, the filter will clog up. So there's a fine balance
9 there. Having too much radial strength, too less. And all of
09:09:50 10 them affect each other. So there's a balance that has to be
11 achieved to get into an optimal window where the filter will
12 perform.

13 Q And how did the team at Bard tackle those challenges of
14 developing a long-term retrievable filter that works in the
09:10:07 15 dynamic environment of the inferior vena cava?

16 A We did a lot of research, literature research, a lot of
17 bench testing. There was animal studies on different
18 prototypes we had. We also benchmarked competitive devices in
19 animals, on the bench. Tried to come up with new test
09:10:32 20 methods. A lot of prototyping. A lot of trial and error,
21 too.

22 MS. HELM: Could you pull up 5967, please.

23 BY MS. HELM:

24 Q Mr. Randall, do you recognize this document?

09:10:51 25 A Yes, I do.

DIRECT EXAMINATION - MICHAEL RANDALL

Q Does Bard conduct a risk/benefit analysis for each of its IVC filters?

A Yes, we do.

Q And as part of Bard's standard operating procedures, is it required to actually complete a risk/benefit analysis?

A It is.

Q And generally speaking, what does a risk/benefit analysis document analyze?

A The risk/benefit analyst document is really going to look at the risks presented to the patient, and also going to look at the benefit it provides to the patient as well.

Q And what is 5967? What is this document?

A This document here is the G2 Risk/Benefit Analysis.

Q And was this document prepared in the ordinary course of business at Bard?

A Yes.

Q And as part of your joining the Bard IVC development team, would you have reviewed and come up to speed on what had happened with prior products before you got involved?

A Yes, for this one.

Q And including a document like this?

A Yes.

MS. HELM: Your Honor, at this time I move to admit 5967.

MR. O'CONNOR: Lack of foundation. I just don't see

DIRECT EXAMINATION - MICHAEL RANDALL

09:12:04 1 a date.

2 THE COURT: Would you lay foundation on that, please.

3 MS. HELM: Can you keep going, Scott.

4 BY MS. HELM:

09:12:49 5 Q Mr. Randall, looking at page 1, are you able to see a date
6 on there? Or anything that indicates what the date is?

7 A No, I can't find that.

8 Q It refers to -- on page 1, it refers to a risk analysis
9 number with a 07 and a DFMEA with 07. Would those be 2007?

09:13:33 10 A It could be, but I'm not sure.

11 MS. HELM: Your Honor, at this time I move to admit
12 5967.

13 MR. O'CONNOR: Foundation and now authentication.
14 There's no signature, no date, Your Honor.

09:13:45 15 THE COURT: Well, it doesn't need to be dated in
16 order to be authenticated.

17 But I think you need to establish through this
18 witness that this is the document that was the risk/benefit
19 analysis.

09:13:56 20 MS. HELM: Thank you, Your Honor.

21 BY MS. HELM:

22 Q Mr. Randall, is 5967 a risk/benefit analysis that was
23 prepared at Bard in the regular course of business?

24 A Yes, it is.

09:14:05 25 Q And are risk/benefit analysis prepared sometimes more than

DIRECT EXAMINATION - MICHAEL RANDALL

09:14:09 1 one time?

2 A There's different revisions of the document, yes.

3 Q And it would have revision numbers? For example this says
4 Revision 1.

09:14:17 5 A Correct.

6 Q And this was prepared in the regular course of business by
7 the engineering department at Bard?

8 A Yes.

9 MS. HELM: Your Honor, at this time I move to admit
09:14:25 10 5967.

11 MR. O'CONNOR: Still objection, Your Honor. I'm
12 looking at Revision 0 and can't tell if this is a final
13 document or what or when in relation to when this witness was
14 at Bard.

09:14:42 15 THE COURT: All right. I'm going to overrule that
16 objection. I think you can bring out all those points on
17 cross-examination, but I don't think it affects admissibility
18 in light of the testimony.

19 5967 will be admitted.

09:14:55 20 (Exhibit 5967 admitted.)

21 BY MS. HELM:

22 Q Mr. Randall, if this document was prepared before you
23 joined the IVC filter development team at Bard, did you take
24 time and go back and look at documents and information about
09:15:07 25 previous filters before you started working on IVC filters?

DIRECT EXAMINATION - MICHAEL RANDALL

09:15:11 1 A Yes. So I worked on the next project, which is G2X, and
2 we needed an RB for that so we would pull this document to
3 help create the RBA for that product.

4 Q This is a document you would have reviewed and relied on
09:15:27 5 as part of your work on the G2X?

6 A Yes.

7 Q Thank you.

8 MS. HELM: And, Scott, if you would turn to page 2.
9 Under Discussion, the first two paragraphs.

09:15:44 10 BY MS. HELM:

11 Q Mr. Randall, can you tell the jury what the discussion is,
12 the first two paragraphs, about the G2 filter's ability.

13 MS. HELM: Oh, Your Honor, may I publish?

14 THE COURT: You may.

09:15:57 15 MS. HELM: Thank you.

16 THE WITNESS: You want me to read or want me to just
17 paraphrase it?

18 BY MS. HELM:

19 Q What about the design of the G2 filter were you discussing
09:16:06 20 in this and about the filter's ability to trap clots?

21 A Yeah. So this discussion here is talking about the G2's
22 design of having a conical design, meaning kind of a cone
23 shape, and it has bilevel filtration. So there's two cones.
24 So the feet of the filter, the legs of the filter, act as trap
09:16:31 25 for clot, and then you have arms that sit above that act like

DIRECT EXAMINATION - MICHAEL RANDALL

09:16:34 1 a trap for the clot.

2 So it's talking about the benefits of the conical
3 design. Bilevel conical design.

4 Q And in this specific risk/benefit analysis, did Bard
09:16:46 5 compare its conical design and bilevel design to other designs
6 such as a competitor's design called the TrapEase?

7 A Yes.

8 Q The jury has heard about the TrapEase and OptEase filters.
9 Do you know, is there a difference between TrapEase and
09:17:02 10 OptEase?

11 A They're essentially the same device except the OptEase
12 has, I believe, the caudal anchors removed. That way you can
13 go and retrieval it from the femoral approach. But other than
14 that, the cage design was the same.

09:17:17 15 Q Do the TrapEase and OptEase filters have conical designs
16 and dual level or bilevel design that the G2 had?

17 A So they do have conical designs, but they're different.

18 The bottom, instead of the cone -- let's I just say
19 this is the cava and the blood's flowing this way.

09:17:40 20 Q Let me interrupt. Would it help you to draw to explain
21 this to the jury?

22 A Yes, it would.

23 MS. HELM: Your Honor, may we approach and draw?

24 THE COURT: Yes, he may.

09:17:50 25 THE WITNESS: Can you hear me?

DIRECT EXAMINATION - MICHAEL RANDALL

09:18:03 1 BY MS. HELM:

2 Q As you draw, if you would explain to the jury what you're
3 drawing.

4 A Is this on?

09:18:13 5 First I'll just show the differences between the
6 filters.

7 THE COURT: Mr. O'Connor, if it would be easier, you
8 can come up here.

9 So this is --

09:18:37 10 MR. O'CONNOR: I'm going to stand over here. Thank
11 you.

12 THE WITNESS: So this is essentially the shape of the
13 two different filters. This is the G2 type design where you
14 have the conical shape here at the bottom, and then the arms
09:18:54 15 provide another conical shape as well.

16 The OptEase filter, this is a conical shape, but it's
17 not facing downward. It's an inverted cone. Then you have a
18 regular conical shape here above.

19 BY MS. HELM:

09:19:11 20 Q And how do they differ as far as clot-trapping ability in
21 the IVC?

22 A So to talk about clot trapping efficiency and how
23 important it is, there's probably one fundamental rule about
24 flow dynamics that you probably need to know.

09:19:39 25 So let's just say this is a river. And flow. These

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09:19:54 1 are lines. These are lines indicating the flow velocity.

2 You'll see the lines in the middle are greatest, the lines at
3 the end are not. So flow in a river, let's say, has the
4 highest velocity in the middle of it.

09:20:16 5 That's why if you see, like, a river, you see where
6 there's a trash buildup, it builds up on the sides because the
7 velocity of the river there is the lowest.

8 Well, the same principle applies to the vena cava.

9 So when designing a filter -- so when designing a
09:20:43 10 filter, and say a clot were to break loose from the legs and
11 flow up, remember flow is going this way, you want to trap the
12 clot in the center of the vena cava where the flow, the blood
13 flow, is the highest. Reason you want to do that is because
14 the blood flow is going to help dissipate that clot over time.

09:21:07 15 Now, for the OptEase design -- sorry for my drawing.

16 For the OptEase design, what happens when blood is
17 flowing this way and clot breaks loose, it traps the clot on
18 the side of the cava where the velocities are the slowest.

19 And there's actually literature reports that show this design

09:21:44 20 to be more thrombogenic compared to other designs. In fact,
21 OptEase is the only filter on the market, and there's several
22 filters, that actually has an inverted cone. And that's one
23 of the reasons why the majority of the manufacturers go with
24 the conical design that's this way instead of inverted conical
09:22:04 25 design on the front end.

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09:22:07 1 Q Thank you, Mr. Randall.

2 A Sure.

3 Q Mr. Randall, you talked about "thrombogenic." That's a
4 term that has particular meaning. Would you explain to the
09:22:34 5 jury what that means.

6 A It means where something is likely to clot off. So
7 thrombogenic, it can cause a clot to build up in itself
8 because you're body's essentially attacking it, the blood
9 flow.

09:22:49 10 Q So you've explained the difference between the G2 and the
11 TrapEase or the OptEase, but you -- we've seen documents where
12 Bard compared itself to the TrapEase the OptEase. Why do a
13 comparison if the filters are so different?

14 A So we did a comparison against the OptEase design because
09:23:09 15 that OptEase design, we consider it a permanent filter, and
16 the comparison we pick for the attribute to compare was for
17 caudal migration when we were testing caudal anchors to
18 improve upon it. So we felt we go for trying to have caudal
19 migration resistance comparable to a TrapEase -- sorry,

09:23:34 20 OptEase design which has a retrieval window of only 14 days,
21 then we felt that that would be a good bar to set when trying
22 to design something for caudal migration resistance.

23 Q And did this similar risk/benefit analysis that was done
24 for the G2, are those done for the G2X, Eclipse, and all of
09:23:56 25 Bard's filters?

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09:23:57 1 A Yes, they are.

2 Q Okay. Thank you.

3 Mr. Randall, I want to switch gears on you a little
4 bit and talk to you. There's a document that this jury has
09:24:06 5 seen many, many times.

6 MS. HELM: Scott, could you pull up 1222, please.

7 BY MS. HELM:

8 Q Are you familiar with this document, Mr. Randall?

9 A Yes, I am.

09:24:16 10 Q And was this a PowerPoint presentation or slide deck for a
11 meeting?

12 A Yes. It was a presentation Andrzej put together for a
13 meeting we were having to kick off the G2 Platinum project.

14 Q Did you attend this meeting?

09:24:34 15 A Yes, I did.

16 Q What was the purpose of the meeting?

17 A The purpose of the meeting was to go and analyze all of
18 the data that existed in EVEREST, in MAUDE, and see if there
19 was improvements we could make to the G2 filter.

09:24:50 20 MS. HELM: And, Scott, would you go to page 6,
21 please.

22 BY MS. HELM:

23 Q Mr. Randall, are you familiar with this diagram?

24 A Yes, I am.

09:24:58 25 Q This has been referred to as a Venn diagram. Is that how

DIRECT EXAMINATION - MICHAEL RANDALL

09:25:02 1 would you characterize it?

2 THE COURT: Hold on just a minute.

3 MR. O'CONNOR: Excuse me, Your Honor. Can we get a
4 date on this document just to put it in context.

09:25:11 5 THE COURT: If you can.

6 MS. HELM: May I publish, Your Honor, first of all?

7 THE COURT: You may.

8 BY MS. HELM:

9 Q Mr. Randall, do you recall approximately when this meeting
09:25:25 10 took place?

11 A Trying to remember when we kicked off Platinum. I think
12 it was 2009 time frame.

13 Q Okay. Thank you. But it was -- based on the document,
14 it's after the EVEREST trial was finished; correct?

09:25:44 15 A Correct.

16 Q And let's go back to our Venn diagram. What does this
17 diagram show?

18 A This diagram shows the different complications that
19 occurred in EVEREST and it shows where there was -- if there
09:26:01 20 was one complication, if another one also existed at the same
21 time.

22 Q Okay. In looking at this Venn diagram, can you tell the
23 ladies and gentlemen of the jury, remind them, how many total
24 fractures occurred during the EVEREST trial.

09:26:23 25 A So the fracture is designate by the little asterisk. So

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09:26:30 1 right there in the center. So there was just one.

2 Q And if I do the math right, there were 18 penetrations
3 reported in EVEREST; right?

4 A Correct.

09:26:42 5 Q How many fractures?

6 A One.

7 Q And there were 15 tilts; correct?

8 A Correct.

9 Q And how many fractures?

09:26:50 10 A That same one.

11 Q And there were ten caudal migrations?

12 A Correct.

13 Q How many fractures?

14 A The same one.

09:26:59 15 MS. HELM: Scott, can you turn to page 13, please.

16 BY MS. HELM:

17 Q The jury's seen this slide a number of times.

18 Do you remember this discussion in your meeting
19 kicking off the G2 Platinum?

09:27:14 20 A Yes.

21 Q What is the goal of Bard each time it's developing a new
22 generation of an IVC filter?

23 A Well, the goal with filters, with any of our products, is
24 continuous improvement. You want to be a leader in a space,
09:27:30 25 you always have to have a best products or always striving to

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09:27:34 1 improve, always striving to advance medicine, always striving
2 to give our customers the best. And the patient.

3 Q And you're always striving to try to reduce or eliminate
4 failure modes?

09:27:45 5 A Oh, yes. And that's what we're trying to do here. If we
6 could reduce these failure modes, we felt we could deliver an
7 even better product.

8 Q As of today, in October of 2018, are you aware of any
9 retrievable IVC filter made by any company that does not have
09:28:07 10 reports of caudal migration?

11 A No, I'm not aware of any.

12 Q As of today, October of 2018, are you aware of any
13 retrievable IVC filter that does not have reports of
14 penetration or perforation?

09:28:21 15 A No.

16 Q My same question: As of October 2018 are you aware of any
17 retrievable filter that does not have reports of tilt?

18 A No.

19 Q And as of today are you aware of any retrievable filter
09:28:34 20 that does not have reports of fracture?

21 A No.

22 Q No one has been able to eliminate all of the adverse
23 events?

24 A All filters exhibit those --

09:28:45 25 MR. O'CONNOR: Objection. Leading.

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09:28:46 1 THE COURT: Hold on.

2 If he stands up, pause for a minute, if you would.

3 Sustained on leading.

4 BY MS. HELM:

09:28:51 5 Q Has any manufacturer of IVC filters that you're aware of
6 been able to eliminate all of those adverse events?

7 A No. They all have them.

8 MS. HELM: You can take that down, Scotty.

9 BY MS. HELM:

09:29:02 10 Q The jury has also seen a couple PowerPoint slides prepared
11 by Natalie Wong related to G2 and G2X filters. Do you know
12 Ms. Wong?

13 A Yes, I do.

14 Q How do you know her?

09:29:14 15 A I've known Natalie 12 years. We started working together
16 on the vena cava filters projects and I've worked with her on
17 other types of projects.

18 Q Over the years and even to the present, do you know
19 whether Ms. Wong has suffered with and battled some
09:29:29 20 significant medical issues?

21 A Yeah. I know she's been out a couple times on medical
22 leave or for some surgeries. Yeah, I think she's still going
23 through some stuff.

24 Q Thank you.

09:29:40 25 Let's talk about the G2X. The jury's heard a lot

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09:29:45 1 about testing on the G2, but I want to bring them forward to
2 the G2X. Was that a filter project you were responsible for
3 at Bard?

4 A Yes, it was.

09:29:54 5 Q Very briefly, would you remind the jury about the
6 difference between two the G2 and G2X.

7 A Yes. So the G2X was we were taking the G2 filter design
8 and we were going to add a snarable hook to the top of the
9 filter, the apex, so clinicians could actually use a snare to
09:30:10 10 go in to retrieve it.

11 Q And because the design change was that hook on the top,
12 were you able to rely on and use some of the previous testing
13 you had done for the G2 to evaluate the G2X?

14 A Yes. If the test testing that had been done before did
09:30:30 15 not affect what we were making a change on, then we were able
16 to use it.

17 Q But did you do additional testing on the G2X?

18 A Oh yeah, we still did a lot of testing on the G2X.

19 Q Did you do any animal testing on the G2X?

09:30:44 20 A Yes, there was an animal study.

21 Q Okay. There's terms about acute animal studies and
22 chronic animal studies. Would you explain the difference,
23 please.

24 A In acute animal studies, it's a short-term study. You're
09:30:57 25 looking at maybe deliverability, retrievability.

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09:31:00 1 The long-term or chronic animal study's where you're
2 actually leaving the filter in for extended periods of time
3 and then coming back at different time points and evaluating
4 it.

09:31:11 5 Q In the long-term or chronic animal studies, are the
6 animals in areas where they're able to roam and free and move
7 around?

8 A For the chronic animal studies, I believe the animals are
9 allowed to roam outside, usually half a day, and then they
09:31:28 10 bring them in at night and they're in bins. Usually about two
11 to four animals per bin. They got space to walk around. But
12 then next day they're outside for the day.

13 MS. HELM: Scott, would you pull up 5384, please.

14 BY MS. HELM:

09:31:45 15 Q And, Mr. Randall, do you recognize this document?

16 A Yes, I do.

17 Q And is this -- what is this document?

18 A It's the Feasibility Acute Animal Study Report for the G2
19 Express, which is also the G2X.

09:32:03 20 Q What is the date on this document?

21 A September 17, 2007.

22 Q Was this Document prepared in the regular course of
23 business at Bard?

24 A Yes, it was.

09:32:13 25 Q And were you involved in the development of the G2 or the

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09:32:18 1 G2 Express at that time?

2 A Yes, I was.

3 MS. HELM: Your Honor, at this time I move to admit
4 5384.

09:32:29 5 MR. O'CONNOR: No objection, Your Honor.

6 THE COURT: Admitted.

7 (Exhibit 5384 admitted.)

8 BY MS. HELM:

9 Q Mr. Randall --

09:32:35 10 MS. HELM: Can we turn to the next --

11 Can we publish?

12 THE COURT: You may.

13 MS. HELM: And can we turn to the next page, Scott.

14 BY MS. HELM:

09:32:41 15 Q And, Mr. Randall, is that your name on the next page?

16 A Yes, it is.

17 MS. HELM: Can you go one more page, Scott.

18 BY MS. HELM:

19 Q This is the test report -- is this the test report for
09:32:51 20 this animal study that you just talked about?

21 A Yes, it is.

22 Q And what was the purpose of this animal study?

23 A The purpose of this animal study was to evaluate the
24 changes that we made by putting a snare hook on the G2 design.

09:33:07 25 So we did some deployment, so filter delivery, and then we

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09:33:13 1 also did retrievals utilizing the Recovery Cone, utilizing
2 different snares to prove out retrievability with that
3 portion.

4 Q And do you recall, did the G2 meet the criteria of the
09:33:25 5 animal study?

6 A Yes --

7 Q G2X. I'm sorry. Did the G2X meet the criteria of the
8 animal study?

9 A Yes, we were successful.

09:33:37 10 Q Mr. Randall, if someone wanted to evaluate all of the
11 testing that Bard performed on its retrievable IVC filters
12 should they also look at the animal studies?

13 A Yes.

14 Q Why?

09:33:48 15 A The animal studies will tell you information about how the
16 product is performing in vivoly. We have bench testing, which
17 is great, but when you're inside a living body, inside a cava,
18 things are different. So you have to do animal studies along
19 with bench testing.

09:34:22 20 MS. HELM: Thank you. You can take that down, Scott.

21 BY MS. HELM:

22 Q In addition to the animal studies, did you also do fatigue
23 testing for the G2X?

24 A Yes, we did.

09:34:26 25 Q If you had already done fatigue testing on the G2 and were

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1 able to carry that knowledge forward, why do fatigue testing
2 on the G2X?

3 A Reason we did fatigue testing on G2X is we're putting this
4 new snare cap on the filter, so that would require us to come
5 up with a new welding process and we wanted to make sure that
6 we did not compromise that weld or the fatigue resistance of
7 the G2X filter by adding that snarable tip on it.

8 Q I want to talk to you briefly about two of the fatigue
9 tests you did on the G2X.

10 MS. HELM: Scott, would you pull up 5385.

11 BY MS. HELM:

12 Q Mr. Randall, you recognize this document?

13 A Yes, I do.

14 Q And what is this document?

15 A This is the G2X Filter Arm Fatigue Comparison.

16 Q And what is the date on this document?

17 A October 25, 2007.

18 Q And was this document part of the testing that you were
19 involved with in the development of the G2X?

20 A Yes, it was.

21 Q And is this document prepared and maintained in the
22 regular course of business at Bard?

23 A Yes, it is.

24 MS. HELM: Your Honor, at this time I move to admit
25 Exhibit 5385.

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09:35:41 1 THE COURTROOM DEPUTY: I show it in on
2 September 20th.

3 THE COURT: Already in evidence.

4 MS. HELM: Oh. I apologize. May I display?

09:35:48 5 THE COURT: You may.

6 MS. HELM: Can you go to the second page, please,
7 Scott.

8 BY MS. HELM:

9 Q And can I -- Mr. Randall, is that your name on the second
09:35:55 10 page?

11 A Yes, it is.

12 MS. HELM: Scott, can you go to page 5, please.

13 BY MS. HELM:

14 Q And is that -- in Section 1, the Purpose, Mr. Randall
09:36:06 15 would you tell the ladies and gentlemen of the jury what the
16 purpose of this test was.

17 A So the purpose of the test is we wanted to compare the new
18 G2X, G2X filter fatigue life to the Recovery and also to the
19 G2 design by conducting a fatigue test to failure.

09:36:30 20 Q Why compare it to the Recovery and G2?

21 A We wanted to compare it to the Recovery and G2 because
22 those devices were already on the market, we know how they
23 perform, and we did not want to have an unintended consequence
24 and perform less than those products. So we needed to
09:36:49 25 maintain the same performance or be better. So that's why

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09:36:52 1 we -- you compare back with this test.

2 MS. HELM: Scott, could you go to page 13, please.

3 And pull up both the graph and Table 7, please.

4 BY MS. HELM:

09:37:07 5 Q Mr. Randall, can you explain to the jury what this table
6 shows.

7 A This is a summary of the data of the comparison after
8 doing the fatigue test.

9 Q And down on Table 7 where it has -- it shows -- does it
09:37:25 10 show what three filters were involved in the comparison?

11 A Yes. The G2 Express, G2, Recovery.

12 Q And what is the mean? Where it says "mean." What does
13 "mean" mean?

14 A Yeah, so mean is basically the average amount of cycles it
09:37:44 15 took to reach that failure.

16 Probably something I just want to clarify on that
17 mean. You look at that number, it's a low number
18 intentionally. So I just want to explain how this test works.

19 So if this is arm of the filter, we're actually
09:38:05 20 putting it inside of a Instron and we have a fixture to
21 deflect the arm up and down a lot. I mean we're using
22 deflections that are not really seen in the IVC. And the
23 reason we do this is because we want it to fail fast. That
24 way, you can do another test on another design, like the G2,
09:38:27 25 Recovery, and have it fail fast and then you can analyze the

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09:38:31 1 results and see how they stack up.

2 So in this particular test you can see the mean is --
3 they look the same for the G2 and G2 Express.

4 Q How do the G2 and G2 Express compare to the Recovery for
09:38:49 5 this arm fatigue test?

6 A They look maybe 11 or 12 times greater.

7 Q And in addition to this arm fatigue test, did you also
8 perform another fatigue test on the G2X?

9 A Yes, we did.

09:39:08 10 Q And what is that test called?

11 A Flat plate fatigue.

12 MS. HELM: Scott, could you pull up 5934, please.

13 BY MS. HELM:

14 Q Mr. Randall, do you recognize this document?

09:39:22 15 A Yes, I do.

16 Q Is your name on it?

17 A Yes, it is.

18 Q What is this document?

19 A This is the protocol for flat plate fatigue testing.

09:39:34 20 So this test here is different from the other tests
21 where we're trying to force a failure. This test here, we're
22 trying to make sure that it passes a certain amount of
23 deflections out to ten years. And it's designed a little bit
24 different --

09:39:53 25 Q Give me just a second.

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09:39:55 1 MS. HELM: Your Honor, at this time I move to admit
2 5934.

3 MR. O'CONNOR: Your Honor, foundation. If we could
4 get a date, please.

09:40:11 5 THE COURT: Are you able to provide a date, Ms. Helm?

6 MS. HELM: Your Honor, I'll look very briefly.

7 BY MS. HELM:

8 Q Mr. Randall, do you recall approximately when you were
9 running this test?

09:40:43 10 A Testing my memory. Maybe 2008 timeframe.

11 Q Again, it says TR-07-02-12. Does that give you any
12 indication it might be in 2007?

13 A It might have. I think the 07, first number, might be the
14 year but I'm not sure exactly.

09:41:16 15 Q But is it your memory that this test was performed during
16 the development of the G2X Express -- or the G2X filter?

17 A Yes, absolutely.

18 MS. HELM: Your Honor, again, move to admit 5934.

19 MR. O'CONNOR: No objection.

09:41:40 20 THE COURT: Admitted.

21 (Exhibit 5934 admitted.)

22 BY MS. HELM:

23 Q Mr. Randall, will you explain what the flat plate fatigue
24 test -- how it worked. Explain to the jury how it worked.

09:41:55 25 A Yes. This test differs completely compared to the cyclic

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09:41:57 1 arm fatigue. So --

2 MS. HELM: Excuse me.

3 May I publish, Your Honor?

4 THE COURT: You may.

09:42:04 5 MS. HELM: I'm falling down the on the job today.

6 BY MS. HELM:

7 Q Go ahead. Apologize for interrupting you.

8 A So we got some new knowledge and learned some things about
9 the IVC that not only does it have radial compression, but
09:42:16 10 there's also a flattening that happens from diaphragmatic
11 forces. So we wanted to emulate that in this test here.

12 So what we did is took a tube, right? You have a
13 tube, you place the filter inside of the tube, and then on the
14 top and bottom of that tube attached to it are flat plates
09:42:38 15 that will squeeze the filter down from 25-millimeters down to
16 14.5. So about 10.5millimeters of deflection. So a severe
17 amount for a diaphragmatic movement.

18 And because this is an accelerated fatigue test and
19 now we're going out millions of cycles, not like the other one
09:43:00 20 where we were forcing it to fail real fast, we're going out
21 millions of cycles, we have to run the test really fast in
22 order to get the data right away. So one of these
23 deflections, we're doing it 40 times per second. So the test
24 is run at 40-hertz. So 40 deflections per second.

09:43:21 25 Q And what was the time period that you were trying to

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09:43:24 1 simulate in this test?

2 A Ten years of implantation life.

3 Q And we're going to talk about that in a minute, but what
4 other body functions were you also trying to simulate in this
09:43:39 5 test? Was it breathing? Was it coughing? What was it?

6 A Yeah, so this diaphragmatic movement. Think of coughing
7 is really how we would try to simulate that type of movement.

8 So coughing has a different -- that occurs at a
9 different rate than, say, breathing.

09:44:02 10 Breathing deflections, they're actually minute.
11 Probably like a millimeter or less. But they occur more. So
12 imagine, you know, regularly doing this, whereas the coughing,
13 right, it's -- it's less frequent but the deflections are
14 more.

09:44:20 15 Q And do you recall how many coughs per hour you were
16 simulating?

17 Mr. Van Vleet told the jury yesterday --

18 A Yeah. So -- so we base the coughing off of a person who
19 has chronic obstructive pulmonary disease and, you know,
09:44:40 20 someone real sick. So they would be coughing 43 times an
21 hour, 24 hours a day. So even in their sleep they're coughing
22 43 times an hour out to 12 years. I'm sorry, ten years.

23 Q And did you actually run this test only to ten years?

24 A No. We ran this test to replicate 77 years.

09:45:10 25 Q 77 years?

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09:45:11 1 A 77 years.

2 Q Okay. If the test standard was ten years, why did you run

3 it to replicate 77 years?

4 A Well, typically we do ten years. That's usually the

09:45:25 5 standard. So it was kind of done in error.

6 Q And the filter -- what were the test results when you ran

7 it to 77 years? The equivalent of 77 years.

8 A I believe we had, oh, I think one fracture at that point

9 in 77 years.

09:45:42 10 Q So at 77 years you got one fracture?

11 A Yes.

12 Q Up until 77 years, how many fractures?

13 A None. So they all passed.

14 MS. HELM: Could we pull up 5929, please.

09:45:56 15 BY MS. HELM:

16 Q And, Mr. Randall, do you recognize this document?

17 A Yes, I do.

18 Q And what is this -- what is this document?

19 A It's the test report for the flat plate fatigue testing.

09:46:18 20 Q If we go back, it also refers to that 07-12-01 and the

21 same project number?

22 A Correct.

23 Q And is your name on this document?

24 A Yes, it is.

09:46:27 25 Q This was document prepared in the regular course of

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1 business for Bard to record the test results for the flat
2 plate fatigue test on the G2X or G2 Express filter?

3 A Yes, it was.

4 Q And was that testing done during the development of the
5 G2X or G2 Express filter?

6 A Yes, it was.

7 MS. HELM: Your Honor, at this time I move to admit
8 5929.

9 THE COURTROOM DEPUTY: I show it in.

10 MS. HELM: After all that.

11 THE COURT: Already in.

12 MS. HELM: May I publish?

13 THE COURT: You may.

14 MS. HELM: Scott, could we go to page 17, section 12.
15 And Conclusions.

16 BY MS. HELM:

17 Q Mr. Randall, would you tell the ladies and gentlemen of
18 the jury what the conclusions were regarding the flat plate
19 fatigue test for the G2X.

20 A Yes. So basically the G2 filters exceeded the ten year
21 requirement for the predetermined acceptance criteria. And it
22 withstood 29 million cycles of coughing, which is equivalent
23 to 77 years of implantation life.

24 Q And what is the final sentence? What is the final
25 conclusion for the test results?

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09:47:37 1 A Therefore the test results are acceptable as no fatigue or
2 corrosion failures were observed at ten years equivalent.

3 Q Again, would you remind the jury when the fatigue
4 occurred? At what year equivalent?

09:47:50 5 A 77.

6 MS. HELM: Thank you. You can take that down.

7 BY MS. HELM:

8 Q Thank you, Mr. Randall, for explaining the testing for the
9 G2X. The fatigue testing.

09:47:59 10 I want to change gears again and talk a little bit
11 about the projects that were going on at Bard relating to its
12 IVC filters. Are you familiar with the various projects that
13 occurred before you arrived and after you arrived at Bard?

14 A Yes, I am.

09:48:15 15 Q And, again, as part of your job when you joined the IVC
16 filter development team, did you go back and learn about the
17 prior projects and the prior filters?

18 A Yes.

19 MS. HELM: Scott, would you pull up 8482, please.

09:48:30 20 BY MS. HELM:

21 Q Mr. Randall, did you assist in preparing a timeline that
22 shows the various dates of the projects relating to Bard's
23 recoverable IVC filters?

24 A Yes, I did.

09:48:42 25 Q And would that timeline assist you in describing to the

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09:48:45 1 jury when these projects occurred?

2 A Yes, it would.

3 MS. HELM: Your Honor, at this time I move to admit
4 8482 for demonstrative purposes only.

09:48:53 5 MR. O'CONNOR: No objection.

6 THE COURT: All right. It's not admitted, but you
7 may display it for demonstrative purposes.

8 MS. HELM: Thank you, Your Honor. May I display?

9 THE COURT: You may.

09:49:02 10 BY MS. HELM:

11 Q Mr. Randall, can you see this timeline?

12 A Yes.

13 Q Okay. On the far left we have the Recovery filter, and
14 that was before you -- was that before you arrived at Bard?

09:49:16 15 A Yes, it was.

16 Q And then the next filter we show is the G2. While the G2
17 was on the market, were there other products -- other projects
18 started at Bard?

19 A Well, yes, there was. Yeah.

09:49:31 20 Q Okay. And there's a G3 on here that appears to have
21 started in 2006. What is that? I don't believe we've heard
22 about the G3 before.

23 A Yes. So the G3 filter was essentially the next generation
24 filter. That's why it's G3. And it was going to be a new
09:49:54 25 platform change. So we were starting out looking at

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09:49:59 1 increasing the legs of the filter to provide more radial
2 strength, which we were thinking would provide more stability
3 of the filter. And this was a filter where we were planning
4 on doing a clinical study to evaluate it to get it to market.

09:50:20 5 Q And was the G3 filter successful -- project successful?

6 A No. The project, we actually stopped the project after
7 doing a bunch of bench testing and ultimately the animal study
8 that put an end to this project because we saw some
9 penetration as a result of the modifications and design
09:50:45 10 changes we were trying to do, so we stopped it.

11 Q Okay. And you talked about you were trying to increase
12 radial strength but you ended up seeing some penetrations as a
13 result of it. You used the term "unintended consequence"
14 previously. Would you explain to the jury what that means.

09:51:05 15 A Yeah. So unintended consequences, we're doing something
16 where we're increasing the radial strength, which does in fact
17 help the filter from not moving up and down, and it does help
18 keep it centered. But the unintended consequence is that you
19 have this focal point of the radial strength of the wire on
09:51:30 20 caval wall and over time it starts to grow out of the cava.

21 I don't know if you've ever seen kind of like a tree
22 next to a fence and sometimes the tree kind of grows through
23 the fence. It's called transmural incorporation. And that's
24 what we saw here. We were seeing a lot of penetration, which
09:51:45 25 was unintended. We did something, it did work, but that was

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09:51:49 1 an unintended consequence.

2 Q Okay. So did the G3 project get past idea and concept and
3 actually get into testing?

4 A Yes. So we do testing in the concept phase. I believe
09:52:06 5 this went to the concept phase where there was extensive bench
6 testing, a bunch of prototypes made, animal study, preliminary
7 biocompatibility. Yeah.

8 Q And then as a result of the unintended consequences, what
9 was decision was made by Bard?

09:52:23 10 A We stopped the project.

11 Q Okay. And then we talked about the G2X today. The next
12 filter on the timeline appears to be the G2 -- or the
13 Platinum. Were you involved in the Platinum project?

14 A I was the project leader initially to kick it off.

09:52:42 15 Q What was the goal of Platinum project?

16 A So the goal of the Platinum project was to improve fatigue
17 resistance, improve caudal migration resistance, improve tilt
18 resistance. And what we wanted to do first is set out to
19 terminally electropolish the filter.

09:53:04 20 Q What's terminally mean?

21 A Terminally means it's the last -- it's the last step. I
22 probably need to explain electropolishing.

23 Electropolishing is an electrochemical process.

24 Basically think of putting a filter inside of some solution,
09:53:26 25 electrolyte solution where there is current involved. When

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09:53:30 1 inside the solution, the solution takes off microns of the
2 surface. So what you're left with is a nice, smooth surface
3 and microimperfections are removed.

4 If you were to look at electropolished versus not
09:53:46 5 electropolished to look at these imperfections, you can't see
6 it with the unaided eye. You need ultra-high magnification to
7 tell. And the reason we're doing that is if you have -- we
8 know from literature that helps improve fatigue resistance.
9 So that's what we were trying to do.

09:54:06 10 Q Was the Platinum project successful?

11 A No, it was not.

12 Q And what did you learn? What happened in the platinum
13 project that resulted in Bard deciding that project was not
14 successful?

09:54:18 15 A So we built some samples and they performed well on bench.
16 They performed well during animal study. But then when we
17 looked at some fatigue testing, what we were seeing is that
18 the wire would break and come out. Then upon further
19 examination, since we were terminally electropolishing the
09:54:48 20 filter, since it's in this electrolyte solution removing
21 surface material, it was also removing surface material of the
22 weld. So inadvertently we were compromising the weld of the
23 filter. So we had to abandon that approach.

24 Q Was that another unintended consequence?

09:55:07 25 A Yes, it was an unintended consequence. We actual had

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09:55:14 1 improved the fatigue life of the wire, but we couldn't
2 implement it in that configuration.

3 Q Okay. We've talked about improving the fatigue life of
4 the wire. After Bard decided that the Platinum project was
09:55:29 5 not going to work, what did Bard do regarding electropolishing
6 and the fatigue life of the wire?

7 A Yeah. So the next project -- so basically the team
8 members for Platinum, we ended that project and then those
9 team members rolled on to the next project, which is called
09:55:46 10 Eclipse.

11 The approach now was we were going to electropolish
12 each component prior to welding it. Which is, if you think
13 about it, electropolishing the whole filter at the very end is
14 easy from the process standpoint. But now we're
09:56:01 15 electropolishing the -- there's 13 components, 12 wires and
16 the tip. So now we've got to electropolish each one by itself
17 and then assemble it together. That way, that weld occurs
18 after electropolishing.

19 Q All right. And on our timeline, when did the shift go
09:56:19 20 from the Platinum and electropolishing the final filter to
21 electropolishing the 13 components?

22 A August of 2009.

23 Q Okay. And once that change was made and your team started
24 working on the Eclipse filter, did you perform testing on the
09:56:40 25 Eclipse filter? Filters made with the electropolished wire?

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09:56:44 1 A Yes, we did.

2 Q Okay.

3 MS. HELM: Scott, you can take that down.

4 BY MS. HELM:

09:56:50 5 Q Let's talk about the some of the tests you performed on
6 the Eclipse filter.

7 MS. HELM: Scott, would you pull up 8575.

8 BY MS. HELM:

9 Q Mr. Randall, do you recognize this document?

09:57:01 10 A Yes, I do.

11 Q What is this?

12 A This is the cyclic fatigue testing of the Vail filter,
13 which is also -- that's the code name for Eclipse, which
14 became the commercial name.

09:57:16 15 Q So internally was the team referring to it as the Vail?

16 A Vail, um-hmm.

17 Q And what is the date of this document? Dates of
18 signatures?

19 A This was signed off in October of 2009.

09:57:29 20 Q And was this document prepared in the regular course of
21 business at Bard?

22 A Yes.

23 Q And was it part of the development of the Eclipse filter?

24 A Yes.

09:57:41 25 MS. HELM: Your Honor, at this time I move to admit

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09:57:44 1 8575.

2 MR. O'CONNOR: No objection.

3 THE COURT: Admitted.

4 (Exhibit 8575 admitted.)

09:57:51 5 MS. HELM: Scott, could you go to page 5, Section 7.

6 BY MS. HELM:

7 Q Mr. Randall --

8 MS. HELM: Can we publish, please?

9 THE COURT: Yes.

09:58:08 10 BY MS. HELM:

11 Q Mr. Randall, would you tell us what this Section 7 tells
12 us about what wires you were testing.

13 A Yes. We were testing the G2X wires and comparing them to
14 the electropolished Eclipse wires.

09:58:29 15 MS. HELM: And can we pull up 8574, please.

16 BY MS. HELM:

17 Q Mr. Randall, do you recognize this document?

18 A Yes, I do.

19 Q Are these the test results for the test we just talked
09:58:45 20 about?

21 A Yes, the results would be in this report.

22 Q What are the sign-off in this document? The dates?

23 A Looks like November and December 2009.

24 Q And was this document prepared in the regular course of
09:58:59 25 business at Bard?

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09:59:01 1 A Yes, it is.

2 Q And was it part of the testing of the development of the
3 Eclipse filter?

4 A Yes.

09:59:09 5 MS. HELM: Your Honor, at this time I move to admit
6 8574.

7 MR. O'CONNOR: No objection, Your Honor.

8 THE COURT: Admitted.

9 (Exhibit 8574 admitted.)

09:59:19 10 MS. HELM: Your Honor, may I publish?

11 THE COURT: Yes.

12 MS. HELM: Scott, can we go to page 10, section 12.
13 Table 7.

14 BY MS. HELM:

09:59:36 15 Q And, Mr. Randall, what does this tell the jury?

16 A This is the results comparing the G2X versus the Eclipse
17 electropolished wires. And the mean, you can see, is 194 for
18 the G2X and the Vail is 345.

19 To give you a little more background about this test,
10:00:04 20 too, this is one test where we put in a severe amount of
21 deflection to force a failure as fast as possible so we can
22 make a comparison.

23 Q Thank you.

24 MS. HELM: You can take that down, Scott.

25

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10:00:15 1 BY MS. HELM:

2 Q In addition to the internal testing, fatigue testing of
3 the Eclipse, did Bard also contact another entity to do some
4 additional testing on electropolished and non-electropolished
10:00:29 5 wire?

6 A Yes. We tested the wire at Fort Wayne, I believe.

7 Q Do you remember the name of the company you used in Fort
8 Wayne?

9 A I think it's --

10:00:40 10 Q Does Fort Wayne Materials sound --

11 A Yeah, Fort Wayne Materials.

12 Q Okay.

13 MS. HELM: Scott, could you pull up 8546, please.

14 BY MS. HELM:

10:00:55 15 Q And Mr. Randall, do you recognize this document?

16 A Yes, I do.

17 Q What is this document?

18 A It was a technical document that Andrzej was preparing to
19 document the rotary beam fatigue testing of various Nitinol
10:01:08 20 wires.

21 Q And was this document -- what was the date on this
22 document?

23 A November 10th, 2008.

24 Q And was this document prepared in the regular course of
10:01:22 25 business in the development of the Eclipse filter?

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10:01:24 1 A Yes, it was.

2 MS. HELM: Your Honor, at this time I move to admit
3 8546.

4 MR. O'CONNOR: No objection.

10:01:32 5 THE COURT: Admitted.

6 (Exhibit 8546 admitted.)

7 MS. HELM: May I publish?

8 THE COURT: Yes.

9 BY MS. HELM:

10:01:41 10 Q And do you see in Table 1, Mr. Randall?

11 A Yes, I do.

12 Q What does that -- what is that telling you? What
13 information is recorded here on Table 1?

14 A Yeah, so if you look at the far right under the Comment

10:01:55 15 section, you see "ingot AP." Those are basically just
16 different processing temperatures of the ingot. So we're
17 looking at the wire that's produced from these ingots and
18 they're processed different and there's fatigue testing done
19 on them to see how they perform. So how processing the wire
10:02:16 20 can actually impact fatigue.

21 Then you have the control sample there that
22 represents I believe the current processing that we have of
23 the G2 type of wire.

24 And then you have two sets of electropolished wire
10:02:33 25 there at the bottom. You'll notice one has .0006-inch per

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10:02:43 1 diameter. That's how much material is removed. Remember I
2 told you electropolishing is just microns removed. So that's
3 why. One had .0006, the other one .0004. So now we're
4 looking at two different electropolishing processes and we're
10:03:00 5 trying to see how they compare.

6 Q Okay. It looks like I see two differences on here. I see
7 differences in temperature and differences in the amount of
8 electropolishing. Why do you test wires at different
9 temperatures?

10:03:16 10 A We're testing at different temperatures because we're
11 trying to see the impact that that has on fatigue and we are
12 trying to optimize the wire processing to optimize fatigue
13 life.

14 MS. HELM: Scott, could we turn to page 3, please,
10:03:34 15 and the conclusion.

16 BY MS. HELM:

17 Q Mr. Randall, can you tell the ladies and gentlemen of the
18 jury what the conclusion of this rotary beam testing was.

19 A It was that the Eclipse wire's equivalent are better than
10:03:46 20 the control wire in that its endurance limit is .65 percent.

21 MS. HELM: Thank you, Scott, you can take that down.

22 BY MS. HELM:

23 Q Mr. Randall, in addition to testing the wires and the
24 fatigue life of the wires, did you also do fatigue testing on
10:04:04 25 the Eclipse filter itself?

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10:04:06 1 A Yes, we did.

2 Q And we've talked about that flat plate fatigue test and
3 you explained it to the jury. Did you perform a flat plate
4 fatigue test on the Eclipse filter?

10:04:16 5 A Yes, we did.

6 Q Okay.

7 MS. HELM: And, Scott, can you pull up 8358, please.

8 BY MS. HELM:

9 Q Mr. Randall, do you recognize this document?

10:04:26 10 A Yes. It's the protocol for the flat plate fatigue.

11 Q And what is the date? What are the sign-off dates on this
12 document?

13 A November 2009.

14 Q And was this prepared in the regular course of business at
10:04:40 15 Bard in the development of the Eclipse filter?

16 A Yes, it was.

17 MS. HELM: Your Honor, at this time I move to admit
18 8358.

19 MR. O'CONNOR: No objection.

10:04:55 20 THE COURT: Admitted.

21 (Exhibit 8358 admitted.)

22 MS. HELM: May I publish, Your Honor?

23 THE COURT: You may.

24 BY MS. HELM:

10:05:02 25 Q Mr. Randall, you said this is the protocol. Is this

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1 actually the test report? Are these actually the results?

2 A Yes, this is a test report. Sorry about that.

3 MS. HELM: And, Scott, could you turn to page 8,
4 section 13, please.

5 BY MS. HELM:

6 Q And can you tell the ladies and gentlemen of the jury what
7 the tests -- conclusions were for the testing of the Eclipse
8 filter under the flat plate fatigue test.

9 A Yeah. So all 12 of the samples passed the acceptance
10 criteria and it also passed the proof loading of five pounds
11 after it was fatigued to show that the weld and legs remained
12 in tact for duration up to ten years.

13 Q Thank you.

14 In addition to the flat plate fatigue test, did you
15 also perform the arm fatigue comparison test on the Eclipse
16 filter?

17 A Yes, we did.

18 MS. HELM: Scott, can you pull up 8359, please.

19 BY MS. HELM:

20 Q And, Mr. Randall, do you recognize this document?

21 A Yes, I do.

22 Q And what is this?

23 A This is the test report for the [[cyclicon fatigue of the
24 Eclipse filter.

25 Q And what is the date for the sign-off on this document?

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10:06:20 1 A November 2009.

2 Q Is your signature on the document?

3 A Yes, it is.

4 Q Was this document prepared in the ordinary course of
10:06:26 5 business at Bard in the development of the Eclipse filter?

6 A Yes.

7 MS. HELM: Your Honor, at this time I move to admit
8 8359.

9 THE COURTROOM DEPUTY: Admitted.

10:06:35 10 THE COURT: It's already in evidence.

11 MS. HELM: Apologize.

12 May I publish, Your Honor.

13 THE COURT: You may.

14 MS. HELM: Scott, if we could go to page 7. In
10:06:46 15 section 12, the data analysis.

16 BY MS. HELM:

17 Q Mr. Randall, can you tell the jury -- and you've explained
18 this arm comparison. Can you tell the jury how the Eclipse
19 compared to the G2X?

10:07:05 20 A Sure. It shows the mean cycles to get the Eclipse filter
21 to fail was 719 and that the mean number of cycles for the
22 standard G2 was 440.

23 Q Okay. We've seen means in other tests that were
24 different. That maybe were higher than the mean in this test.

10:07:25 25 Can you explain why there would be differences in test results

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10:07:30 1 on the same type of test?

2 A Sure. So the cyclic arm fatigue test is a test that, if
3 you're going to make a comparison, you have to test the
4 samples at the exact same time, on the exact same piece of
10:07:46 5 equipment, using the exact same fixturing because it's a
6 comparison test and utilizing the same deflection.

7 So if we were to test it here and then I used the
8 fixture on a different tester, it wouldn't be applicable.
9 This is a test where you have to do it at the same time if
10:08:04 10 you're going to make a comparison.

11 Q Okay.

12 MS. HELM: Scott, could you pull up 8482, please.

13 And may I publish, Your Honor, as a demonstrative?

14 THE COURT: Yes.

10:08:17 15 MS. HELM: Thank you.

16 BY MS. HELM:

17 Q Mr. Randall, we talked about the G3, the G2X, the
18 Platinum, and the Eclipse. I want to briefly switch to the
19 Meridian and the Denali.

10:08:29 20 Were those two other projects that Bard started
21 working on in 2009?

22 A Yes.

23 Q And did you work on either of those projects?

24 A Yes. They were both underneath me.

10:08:40 25 Q Okay. And looking at the timeline, and we'll talk about

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10:08:45 1 it in a minute, when was the Meridian filter cleared by the
2 FDA and available for Bard to sell commercially?

3 A August 2011.

4 Q The jury's heard a lot about the Meridian and I'm not
10:09:02 5 going to go through it all, but the jury's also heard Bard
6 knew about caudal migration and the concept of caudal anchors
7 as far back as 2006 on our timeline.

8 What was the design change to the Meridian?

9 A The design change to the Meridian is we actually figured
10:09:19 10 out a way of welding titanium anchors onto the arms. And we
11 need two types of anchors. One anchor was going to go on the
12 wrist of the arm, and on an alternating arm the other anchor
13 would go on the shoulder. And that needed to be done because
14 this IVC filter needs to fit in diameters that are large and
10:09:45 15 small.

16 So on the small diameter, that wrist anchor turns
17 away from the wall so it can't engage the wall to prevent the
18 downward movement. But now that shoulder anchor engages the
19 wall in a smaller diameter and vice versa on the larger side.

10:10:06 20 Q Okay. But if we know -- if Bard knew about caudal
21 migration and knew about the concept of caudal anchors way
22 before 2009, why did it take so long for Bard to develop and
23 incorporate this design change?

24 A I'm sorry, can you repeat that question.

10:10:23 25 Q Sure. If Bard knew about caudal anchors prior to the

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1 development of the Meridian, why did it take Bard so long to
2 develop them and get the Meridian on the market?

3 A Sure. So we didn't have the design early on. The G3 --
4 the approach was to make the legs stronger and go at it from a
5 radial strength standpoint to help improve caudal migration.
6 But we had unintended consequence there.

7 So it wasn't until we found a material which we could
8 actually weld on the Nitinol, which is titanium, and came up
9 with a design in that process that we're able to come up with
10 a design we can finally commercialize.

11 Q When have a timeline that shows these various projects.
12 Did your design team learn from the projects that were not
13 successful.

14 A Oh, absolutely.

15 Q And how did you take what you learned and incorporate it
16 moving forward?

17 A Yeah. I mean, if you look at what we learned in the G3,
18 we learned there's a fine balance between radial strength and
19 wall apposition. So some of those learnings that went into
20 that helped us refine Denali in terms of its radial strength,
21 adding penetration limiters.

22 The learning that we found out from the Platinum
23 project about terminally electropolishing, we knew we couldn't
24 terminally electropolish at the very end if there was a weld
25 that we were going to be electropolishing.

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10:11:51 1 So Denali is terminally electropolished, but it
2 doesn't have that weld.

3 So everything we've learned from previous projects we
4 moved forward. Meridian, we learned about the caudal anchors.
10:12:06 5 We incorporate that into Denali. So it's kind of building up.
6 You have this pool of knowledge and things you learned through
7 projects that fail that you take with you. So it's continuous
8 learning, too.

9 Q Also appears that the Denali project started in 2009.

10:12:26 10 Very briefly you've explained it. Explain the significant
11 difference between the wires in the previous generation
12 filters and what you used in the Denali.

13 A Yeah. So if you look at the G2 series platform, there's
14 12 wires and then you have a tip. Either bullet tip for the
10:12:47 15 G2 design or a snarable tip.

16 For the Denali filter, the way we actually
17 manufacture that is similar to a stent where we take a Nitinol
18 tubing and then we laser cut the design. So we'll laser cut
19 the arm, we'll laser cut the anchors, we'll laser cut the
10:13:04 20 caudal anchors, the cranial anchors, the penetration limiters.
21 And then you have this tube that's essentially sliced up and
22 then you expand it. So then we have a fixture. And then you
23 heat set it. So I don't have that weld now. Now I can
24 terminally electropolish.

10:13:24 25 Q And when was the Denali available for Bard -- cleared by

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1 the FDA and available for Bard to sell commercially?

2 A May 2013.

3 Q Mrs. Hyde, the plaintiff in this case, her filter was
4 implanted in February of 2011. At that time, was the Meridian
5 cleared by the FDA and available for sale?

6 A No, it was not.

7 Q After Bard submitted it's 510(k) to the FDA for the
8 Meridian, did Bard continue to conduct testing on the Meridian
9 through 2011 including after February of 2011?

10 A Yes. We were -- we're going back and forth with the FDA
11 with follow-up questions and they wanted to see additional
12 testing. So there was still testing going on prior to that.

13 Q Mr. Randall, you've talked about your goal and your
14 approach towards designing IVC filters. And you've talked
15 about the fact you haven't been able to fully eliminate all of
16 the adverse events in IVC filters.

17 If you believed that the G2X or the Eclipse filters
18 that the risk of those filters outweighed the benefits, what
19 would you have done?

20 A I would have spoke up and said something.

21 Q At any time that you were at Bard, did you ever believe
22 that the risks of the G2X or the Eclipse filters outweighed
23 the benefits those filters were providing to patients?

24 A No.

25 Q Did you make decisions to cancel projects after the

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1 company had spent tremendous amounts of money on them?

2 A Did I make decisions to cancel? Oh, yes, absolutely.

3 Q And were those decisions based on the fact you felt like
4 the risk outweigh the benefits of those projects?

5 A Yes.

6 Q Today do you still believe that the risk -- that the
7 benefits of G2X and the Eclipse outweigh the risks that we've
8 seen in the adverse events?

9 A Yes, absolutely.

10 MS. HELM: Thank you.

11 THE COURT: Cross-examination.

12 MR. O'CONNOR: I'm going to need a minute to get
13 organized here.

14 C R O S S - E X A M I N A T I O N

15 BY MR. O'CONNOR:

16 Q Hello, Mr. Randall. How are you doing today?

17 A Doing well. Thank you.

18 Q Thanks for coming back.

19 Mr. Randall, I want to start with questions about
20 something that defense counsel asked you early on in your
21 testimony, and that's whether you were aware of any other
22 filters as of today that don't have failures. Do you recall
23 that testimony?

24 A Yes.

25 Q And you were suggesting that Bard's like all the rest;

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10:16:42 1 right? Bard has failures just like every other filter on the
2 market; true?

3 A Yes. To my knowledge.

4 Q And that's something that I think you would agree that you
10:16:56 5 should research or you did research before you came down here
6 to talk to this jury. True?

7 A True.

8 Q All right. Felice, can we show Mr. Randall Exhibit 1940,
9 please.

10:17:10 10 1940. May I publish to the jury, Your Honor?

11 THE COURT: Yes, Your Honor.

12 BY MR. O'CONNOR:

13 Q Mr. Randall, this is a chart that we've talked to other
14 witnesses about in this case. As you can see, it's a chart
10:17:25 15 that includes other manufacturer filters on the left. Do you
16 see that?

17 A Yeah. I haven't seen this before but, yes, I can see
18 other manufacturers, yes.

19 Q Sure. And then as we look across at that top row, you can
10:17:46 20 see it says Manufacturer Brand Name and then it talks about
21 total MDRs. You know what those are; right?

22 A Yes.

23 Q Medical device reports; right?

24 A Correct.

10:17:57 25 Q And that means failures, complications, that are reported

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10:18:00 1 to the company, to the MAUDE database; right?

2 A Correct.

3 Q And that's an important function, too, isn't it,
4 Mr. Randall, for a company like Bard to pay attention to
10:18:11 5 what's going on with its filters when they reach patients?
6 Right?

7 A Yes, we have a field assurance group.

8 Q And you talked about testing and all of the testing that
9 was done, but one way that you -- one reason to use testing,
10:18:24 10 important reason, is to provide predictability, how the
11 filterer will actually behave once it's implanted in a human
12 being; true?

13 A True.

14 Q And that's important; correct?

10:18:34 15 A Correct.

16 Q And you do everything and you hope that your tests are
17 right.

18 A Correct.

19 Q And so if we look at this, though, Mr. Randall, and I can
10:18:45 20 tell you --

21 MR. O'CONNOR: Felice, if you can show Mr. Randall
22 down towards the bottom.

23 BY MR. O'CONNOR:

24 Q This is Bard data from TrackWise through July 2010. We
10:18:54 25 don't really have anything up to today, but I can tell you

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10:18:58 1 this: Mr. Modra said that would be pretty easy for Bard --
2 well, Bard could put that together. But there you see July
3 2010.

4 MR. O'CONNOR: Thanks. Take that down, Felice.
10:19:08 5 Appreciate that.

6 BY MR. O'CONNOR:

7 Q As you can see, as we go along the total Bard row --

8 MR. O'CONNOR: Felice, can you highlight that.

9 Very good. Thank you.

10:19:25 10 Lift it up so we can see the Total Competitors above.

11 BY MR. O'CONNOR:

12 Q All right. The jury will see this. But as you can see,
13 for total MDRs, Bard filters as of 2010, including the
14 Recovery, G2, G2X, and the Eclipse, have 1,202 MDRs. Do you
10:19:55 15 see where I'm reading?

16 MR. O'CONNOR: Felice, it might be easier for
17 Mr. Randall to see the whole chart in context.

18 BY MR. O'CONNOR:

19 Q Do you see that, sir?

10:20:18 20 A Yes, I see the column now.

21 Q Do you see over by where it has device migrations, do you
22 see that for the Bard filters?

23 A Yes.

24 Q And that's comparing to a number of different competitors.
10:20:35 25 Bard had 262 migrations, do you see that?

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10:20:39 1 A Yes.

2 MR. O'CONNOR: And then, Felice, let's show
3 Mr. Randall fractures for Bard filters.

4 Total. Total fractures, Felice. Thanks.

10:20:57 5 BY MR. O'CONNOR:

6 Q You see, Mr. Randall, where Bard had 355 total fractures
7 compared to 80 for all those competitors? Do you see that?

8 A Yes. Total numbers. Yes.

9 Q You see the numbers. I'm saying those numbers correctly;
10:21:13 10 right?

11 A Yes.

12 Q Then that's fractures.

13 MR. O'CONNOR: And then, Felice, let's show
14 perforations to Mr. Randall.

10:21:32 15 Go down to the total for Bard, Felice, if you can
16 show him that.

17 BY MR. O'CONNOR:

18 Q You see, Bard had a total of 254 perforations as of
19 July 2010. Do you see that?

10:21:54 20 A I see.

21 Q And these events, these should be reported to the MAUDE
22 database; correct?

23 A They should. It said the data was from TrackWise?

24 Q Well, TrackWise is a system within Bard; correct?

10:22:14 25 THE COURT: Hold on just a minute, Mr. O'Connor.

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10:22:17 1 MS. HELM: Object. This exceeds the scope of direct
2 examination. I don't believe we had any discussion about
3 rates.

4 MR. O'CONNOR: Your Honor, they went and talked about
10:22:26 5 filters and all filters have failures. I think they opened
6 the door to this testimony.

7 THE COURT: Overruled.

8 BY MR. O'CONNOR:

9 Q Let me ask you this, Mr. Randall, TrackWise is a system
10:22:38 10 within Bard; correct?

11 A Yes.

12 MR. O'CONNOR: Felice, put up 691. We talked about
13 that. And, Felice, here's the paragraph that is important to
14 me about this. That paragraph there. 6991.

10:23:04 15 If you could, this is on the FDA Alert, Your Honor,
16 6991, and I would like to publish to the jury.

17 THE COURT: You may.

18 MR. O'CONNOR: Felice, do you have that paragraph?

19 Just that second paragraph.

10:23:38 20 BY MR. O'CONNOR:

21 Q All right. Now, Mr. Randall this is a document that was
22 discussed yesterday by various witnesses and, as you can see,
23 since 2005 the FDA received 921 device adverse event reports
24 involving the IVC filters. Do you see where I read?

10:23:57 25 A Yes, I do.

CROSS-EXAMINATION - MICHAEL RANDALL

10:23:59 1 Q And I showed you a moment ago in terms of adverse event
2 reports, as of 2010 we just saw a record where Bard had 1,202.
3 Do you recall that?

4 A Yes. On that document?

10:24:17 5 Q Yes. And then as you can see as we go on, it talks about
6 FDA received 328 complaints of device migration. Do you see
7 where I'm looking at?

8 A Yes, I do.

9 Q And I just showed you in the Bard's internal document
10:24:35 10 where Bard since 2010 recorded 262 migrations during the same
11 period of time. July 2010 was what I showed you in Bard.
12 This is August 2010. Do you recall that?

13 A Yeah, so I'm not really familiar with that other document.

14 Q I'm just -- just talking numbers right now, sir.

10:24:58 15 A Okay.

16 Q And then finally perforation. It says the FDA received 70
17 complaints of perforation. Do you see that?

18 A Yes.

19 Q And as of July 2010 in the table prepared by Bard I showed
10:25:18 20 you where Bard was aware of 254 perforations with it's
21 filters. Do you recall that?

22 A It said that on the table.

23 Q Thank you.

24 Now, sir -- I need to find your exhibit. Where's the
10:25:41 25 graph? What number is it? I wanted to put up the defense

CROSS-EXAMINATION - MICHAEL RANDALL

1 timeline that Mr. Randall had. Do you have an exhibit number
2 on that?

3 Oh, here we go.

4 Can we put up 8482.

5 MS. REED ZAIC: It's a demonstrative.

6 MR. O'CONNOR: Could we have the demonstrative up,
7 please, Scott.

8 BY MR. O'CONNOR:

9 Q All right. This is the timeline, and you were kind enough
10 to show us when these actual projects started.

11 MR. O'CONNOR: May I publish this to the jury, Your
12 Honor?

13 THE COURT: You may.

14 BY MR. O'CONNOR:

15 Q But, Mr. Randall, caudal anchors were known to Bard way
16 back in 2006; correct?

17 A The concept of stopping -- not a design. A feature.
18 Caudal anchors really just means stop movement down. But it's
19 not a design.

20 Q That's fine. But we've seen documents, sir, where Bard
21 was aware that caudal anchors -- they believed early on caudal
22 anchors could stop caudal migration and that in turn would
23 reduce or minimize other failures including tilt, perforation,
24 and fracture; true?

25 A There was a hypothesis.

CROSS-EXAMINATION - MICHAEL RANDALL

10:27:31 1 Q Well, it was a hypothesis that Bard continued with when it
2 finally put out the -- when it finally got the Meridian out on
3 the market; right?

4 A Yes, it was a hypothesis when we put that out.

10:27:45 5 Q So Bard knew the G2, G2X, was caudally migrating; right?

6 A There was observed caudal migration, absolutely.

7 Q And Bard knew the Eclipse was caudally migrating; true?

8 A We knew that there's -- well, small amounts of caudal
9 migration.

10:28:02 10 Q But the Eclipse is essentially the G2X with
11 electropolishing; right?

12 A Yes.

13 Q We talked about that before.

14 And Bard knew, at least had this hypothesis, this
10:28:13 15 concern, that if a filter was going down, it could tilt, it
16 could perforate, it could fracture, and those fractures could
17 go into different parts of a patient's body; true? That was
18 the hypothesis, that was the concern.

19 A The hypothesis was that if we can make the filter more
10:28:28 20 stable so it doesn't move down, that we might be able to get
21 benefit for those other complications. But that was later
22 proven wrong.

23 Q Well you had the Meridian out on the market; right?

24 A In August of 2011. Right.

10:28:43 25 Q And you knew the G2X and the G2 were caudally migrating,

CROSS-EXAMINATION - MICHAEL RANDALL

1 were tilting, were fracturing, and were migrating. We just
2 looked at a table of that. You do know that; right?

3 A Yes, there were reported complications.

4 Q Bard made a choice to keep the G2, G2X, and Eclipse on the
5 market knowing it was developing a filter with caudal anchors;
6 right?

7 A Yes, but complications were well below one percent.

8 Q I'm not asking you about complication rates, sir. I'm
9 just asking you, Bard knew that the G2, G2X, and Eclipse were
10 migrating and perforating and tilting; yes?

11 A The reported rates, yes.

12 Q And Bard knew --

13 THE COURT: Mr. O'Connor, we're going to break at
14 this point.

15 Members of the jury, we'll resume at 10:45.

16 (The jury exited the courtroom at 10:29.)

17 THE COURT: You can step down.

18 Counsel, where are we on time overall?

19 MR. ROGERS: This is our last witness, Your Honor,
20 and we will rest.

21 THE COURT: After this witness?

22 MR. ROGERS: Yes, Your Honor.

23 THE COURT: How much more do you have, Mr. O'Connor?

24 MR. O'CONNOR: I'm going to try -- my goal is five
25 minutes, but in dog years probably ten minutes. 10, 15

CROSS-EXAMINATION - MICHAEL RANDALL

10:30:16 1 minutes.

2 THE COURT: I will make no comment.

3 MR. O'CONNOR: I'm not good at math, as we all know.

4 THE COURT: All right. So we're going to be done
10:30:29 5 with the evidence by 11 o'clock; right?

6 MR. ROGERS: I think that's correct, Your Honor.

7 THE COURT: Okay. What I think I'm going to be
8 inclined to do, then, is to instruct the jury and then break
9 for lunch even though it will be 11:20 or 11:30. That way
10:30:51 10 we're not starting an argument and having it go a half hour
11 and breaking for lunch. Or, you know, going 45 minutes into
12 the lunch hour for the jury. Does that make sense to you all?

13 MR. ROGERS: It does to me.

14 THE COURT: Well, wait. We haven't talked about
10:31:06 15 rebuttal evidence.

16 MR. O'CONNOR: Julia --

17 I think at some point in time, Your Honor, we're
18 going to be making a motion; am I right?

19 MR. GOLDENBERG: Your Honor, we're going to be making
10:31:15 20 a 50(a) motion at the end of the case.

21 MS. REED ZAIC: 50(a).

22 THE COURT: Let's plan to have you make that -- well,
23 first, are you going to do any rebuttal evidence?

24 MR. ROGERS: Why are you looking at me?

10:31:35 25 MR. O'CONNOR: I forgot to tell you.

CROSS-EXAMINATION - MICHAEL RANDALL

10:31:36 1 No. As far as I know --

2 THE COURT: Okay. So what I think what we ought to
3 do is defense will rest, plaintiff will indicate you've got no
4 rebuttal evidence.

10:31:47 5 I think I will then instruct the jury, then we'll let
6 them go and you can make the 50(a) motion, which I'll consider
7 before the jury comes back. That way we don't keep the jury
8 waiting.

9 MR. GOLDENBERG: Your Honor, the only concern I have
10:32:00 10 is by reading the instructions, one of our -- the 50(a) motion
11 is on the inherent characteristic.

12 THE COURT: Oh. I see. Okay. So I do need to rule
13 on that before I instruct.

14 Well, then what I think we'll do is finish the
10:32:14 15 evidence, then I'm going to take another break and excuse the
16 jury for ten minutes, tell them I need to rule on a legal
17 issue before I instruct, we'll hear the 50(a) motion, then
18 bring them back in and instruct them and then break for lunch.

19 MR. GOLDENBERG: Very good.

10:32:32 20 THE COURT: Okay. If we can be back at quarter to,
21 we'll not keep the jury waiting too long.

22 (Recess taken from 10:32 to 10:44. Proceedings resumed
23 in open court with the jury present.)

24 THE COURT: Thank you. Please be seated.

10:47:23 25 You may continue, Mr. O'Connor.

CROSS-EXAMINATION - MICHAEL RANDALL

10:47:34 1 BY MR. O'CONNOR:

2 Q Thank you for coming back, Mr. Randall.

3 So the G2, G2X, and the Eclipse stayed on the market
4 during the development of the Meridian; true?

10:47:46 5 A True.

6 Q Thank you. Now, you talked about the G2 Platinum. That
7 was a device where you had discussed caudal anchors, do you
8 recall that?

9 A It was a project where we were going to implement -- or
10:48:04 10 try to come up with caudal anchors for it.

11 Q And I think, according to your chart, you started that
12 project back in about 2008, does that remember -- does that
13 sound correct?

14 A I believe so.

10:48:16 15 Q And you decided to cancel it. Do you recall that?

16 A Yeah, we were unsuccessful.

17 MR. O'CONNOR: Felice, could you put up Exhibit 1222.

18 I believe this is in evidence, Your Honor.

19 THE COURT: Yes, it is.

10:48:41 20 MR. O'CONNOR: May I publish to the jury?

21 THE COURT: You may.

22 MR. O'CONNOR: And can we go to page 3, Felice.

23 BY MR. O'CONNOR:

24 Q And, sir, this is a PowerPoint. I think it's been talked
10:48:55 25 about a couple times, I think you talked about it. Do you

CROSS-EXAMINATION - MICHAEL RANDALL

10:48:57 1 recall?

2 A Yes.

3 Q And here the PowerPoint says "G2 Platinum. The objective
4 is to improve the G2 platform to address current complications
10:49:09 5 without a clinical trial."

6 Did I read that correctly?

7 A Correct.

8 Q And at the bottom it says "Risks." Do you see where I'm
9 reading from?

10:49:20 10 A Yes.

11 Q And the Risks says: Unable to make changes to the filter
12 without a critical trial -- clinical trial, excuse me.
13 Timeline challenges based on changes.

14 Now, did I read that correctly?

10:49:36 15 A Yes.

16 Q And that's a project you decided to stop; right?

17 A Yeah. We had other projects that would have a clinical --

18 Q Sir, I'm just talking about this one. You decided to stop
19 the G2s Platinum, did I understand you correctly before? Yes
10:49:53 20 or no?

21 A Yes, we stopped it.

22 Q Thank you.

23 Now, the Eclipse, let's talk about that for a moment.

24 MR. O'CONNOR: And, Felice, let's put up Exhibit

10:50:11 25 4416.

CROSS-EXAMINATION - MICHAEL RANDALL

10:50:16 1 I believe this is in evidence, Your Honor.

2 THE COURT: Yes, it is.

3 MR. O'CONNOR: May we publish to the jury?

4 THE COURT: You may.

10:50:33 5 BY MR. O'CONNOR:

6 Q On April 27, 2010, there's another writing by Bard that
7 discusses Eclipse anchors, caudal anchors, do you see that,
8 sir?

9 A Yes.

10:50:43 10 Q And under Value Proposition it says that "The Eclipse
11 anchor filter will retain the advantages of the G2, G2X,
12 Eclipse, including the retrievable indication, while improving
13 caudal migration resistance."

14 Did I read that correctly?

10:51:01 15 A You did.

16 Q "This improvement in caudal migration resistance should
17 reduce tilt, fracture, and penetration."

18 Did I read that correctly?

19 A Yes.

10:51:15 20 Q And then there's a discussion about the naming rationale.
21 Do you see that down there in the next paragraph?

22 MR. O'CONNOR: Felice, can you enlarge that
23 paragraph. Those two paragraphs.

24 BY MR. O'CONNOR:

10:51:33 25 Q This is talking about the Eclipse -- you were involved in

CROSS-EXAMINATION - MICHAEL RANDALL

1 the Eclipse, right? You talked to us about electropolishing.

2 A Yes.

3 Q And it says "The Eclipse launch introduced a product that
4 addressed a shortcoming with its predecessors G2X and G2
5 through electropolishing."

6 Did I read that correctly?

7 A I'm sorry, where are you at?

8 Q I'm sorry, sir, I'll have Felice highlight it.

9 Right under Naming Rational. I'll read it to you,
10 and you tell me if I read it correctly. Okay?

11 A Okay.

12 Q It says "The Eclipse launch introduced a product that
13 addressed a shortcoming with it's predecessors G2X and G2
14 through electropolishing."

15 Did I read that direct correctly?

16 A Yes.

17 Q And that's a point you were trying to make to the jury
18 before; right? The electropolishing and difficulties but how
19 you were able to do it on the Eclipse and you showed us the
20 test. Do you recall that?

21 A Yes.

22 Q Thank you. And it goes on to say --

23 MR. O'CONNOR: Felice, if you could highlight the
24 next sentence.

25

CROSS-EXAMINATION - MICHAEL RANDALL

10:52:29 1 BY MR. O'CONNOR:

2 Q It goes on to say, "The change in brand name and codes was
3 to create a break with the baggage associated with the
4 previous versions despite the fact that the new iteration was
10:52:47 5 the same as G2X in every way but one."

6 Did I read that correctly?

7 A You read that correctly.

8 Q It goes on to say, "The name has been well received and
9 the strategy has worked both internally and in some cases with
10:53:09 10 former customers."

11 Did I read that correctly, sir?

12 A Yes.

13 Q So I just want us to keep this date, April 27, 2010, in
14 mind because it's a date where you're still talking about
10:53:24 15 caudal anchors and it's a date where there's some reminiscing
16 and discussion and talk about the Eclipse and why that came on
17 the market. You see in there; yes?

18 A Yes.

19 Q All right.

10:53:37 20 MR. O'CONNOR: Felice, let's go to Exhibit 4842.

21 I believe this is in evidence, Your Honor.

22 THE COURT: Yes, it is.

23 MR. O'CONNOR: May I publish to the jury?

24 THE COURT: You may.
25

CROSS-EXAMINATION - MICHAEL RANDALL

10:53:56 1 BY MR. O'CONNOR:

2 Q So, Mr. Randall, there were discussions about when the
3 Meridian would get on the market with the caudal anchors. You
4 told us that it was still going on in August of 2011. But I
10:54:08 5 want you to look here. This is an e-mail from Bret Baird to
6 other people at Bard and it's dated March 8, 2011. Do you see
7 that?

8 A Yes.

9 Q And now, to put everything in context, Bard is developing
10 caudal anchors, which it knows and believes will reduce
11 migration which will in turn reduce tilt, migration, fracture.
12 Right? We just saw that.

13 A I'm sorry, can you repeat that. I was reading the
14 document.

10:54:39 15 Q Sure. We just saw a document where Bard had been talking
16 about caudal anchors even before 2010 and the belief being
17 this improvement in caudal migration resistance should reduce
18 subsequent tilt, fracture, and penetration. You recall I read
19 that to you from this prior document.

10:54:56 20 A Yes.

21 Q That's April 27, 2010.

22 And Eclipse, as you told us, was on the market and it
23 was electropolishing just to stay there knowing the Meridian
24 was going to come out on the market; right?

10:55:10 25 A Yeah, the Meridian would follow.

CROSS-EXAMINATION - MICHAEL RANDALL

10:55:12 1 Q But look what happens. Here we are March 8, 2011, and
2 Bret Baird writes to the district managers, the DMs. You know
3 who they are.

4 A Yes, I know we have DMs. I don't necessarily know all of
10:55:25 5 them.

6 Q I thought you told us when you came over last week you do
7 work with salespeople to help them understand about filters.

8 A We have many DMs, I just don't know all of them.

9 Q That's fine. These DMs. You're on this e-mail, do you
10:55:40 10 see that?

11 A Yes, I do.

12 Q Now we're on March 8, 2011. G2, G2X and the Eclipse are
13 on the market, and here's the word from Bard.

14 "In the next day or so we will be going on backorder
10:55:51 15 for the femoral G2 filter as a result of the Meridian delay."

16 Do you see where I read?

17 A Yes.

18 Q Did I read it correctly?

19 A Yes, you did.

10:56:02 20 Q "As you are aware, we had been working to finish the
21 remaining G2 product preparation -- in preparation for
22 discontinuation."

23 Did I read that correctly?

24 A You did.

10:56:12 25 Q "But with the Meridian delay, we have turned production

CROSS-EXAMINATION - MICHAEL RANDALL

1 back on temporarily. We should be out of backorder by next
2 week."

3 Now, do you see where I read?

4 A Yes.

5 Q Nothing had changed by this time with the G2 or the G2X in
6 terms of design; right? Design had always been the same from
7 day 1; correct?

8 A You're talking about in 2011, March?

9 Q Yeah. The G2 always stayed the G2. You never changed the
10 design of the G2 and called it the G2, it always remained the
11 G2; correct?

12 A Yes, G2. Correct.

13 Q We know from what we talked about that the G2 Bard was
14 aware it was caudally migrating, that it was perforating, that
15 it was tilting, and it was fracturing. You recall that
16 testimony; correct?

17 A Yes, there were reports of complications.

18 Q But rather than discontinuing sales altogether and telling
19 the medical community we've got caudal anchors coming, don't
20 use our device, Bard made a choice to keep the G2 on the
21 market. Correct? You can see that in this document.

22 A Correct.

23 Q Now, let's go to -- oh, and by the way, that e-mail talked
24 about the G2 not the Eclipse; right? The one we just looked
25 at.

CROSS-EXAMINATION - MICHAEL RANDALL

10:57:45 1 A I didn't read the whole thing. I --

2 MR. O'CONNOR: Go ahead and put it back up, Felice.

3 BY MR. O'CONNOR:

4 Q Mr. Baird's e-mail is that the G2 needs to be continued
10:58:01 5 for a period until they can get the Meridian out. He's not
6 talking about the Eclipse, is he?

7 A No, I don't see any Eclipse reference in there.

8 Q Now, let's talk about Exhibit 5385.

9 And, by the way, just to kind of go back to put this
10:58:23 10 in context, you were kind enough -- you talked to me about
11 bench testing, and that's to give a medical device company
12 predictability on how a filter will behave out there when it's
13 in human beings; right?

14 A To the best we can.

10:58:37 15 Q And you talked about animal studies and you showed us one
16 where the filter was actually implanted in pigs. Do you
17 recall that?

18 A Yes.

19 Q And then you talked about the EVEREST study. That was the
10:58:47 20 G2 study; correct?

21 A Yes. And that --

22 Q That was a study that was for a finite period of time;
23 right?

24 A Yes.

10:58:57 25 Q And in that period of time, as you told us before, Bard

CROSS-EXAMINATION - MICHAEL RANDALL

10:59:01 1 discovered failures; right?

2 A There were reported adverse events in that.

3 Q We can look at that Venn diagram. But there were, of 83
4 patients, for example -- well, the jury can see it. I'm

10:59:21 5 trying to move along quickly here. But there were
6 complications in that finite period of time; right?

7 A Yes.

8 Q So Bard knew that within 180 days the G2 was demonstrating
9 failures; right? From that study.

10:59:36 10 A I don't know the time period of that study.

11 Q All right. Let's assume --

12 A But there were reported adverse events in it, though.

13 Q And as a matter of fact, that raised issues that you
14 talked about in your PowerPoint; right?

10:59:50 15 A I don't follow the question.

16 Q We'll come to the PowerPoint in a moment.

17 But here's the point. So you talked to us about this
18 arm fatigue comparison before. Do you recall that?

19 A Yes.

11:00:11 20 MR. O'CONNOR: May I publish?

21 THE COURT: What are you publishing?

22 MR. O'CONNOR: It is published?

23 THE COURT: What are you publishing?

24 MR. O'CONNOR: I'm sorry, Your Honor. 5385.

11:00:19 25 THE COURT: You may.

CROSS-EXAMINATION - MICHAEL RANDALL

11:00:22 1 BY MR. O'CONNOR:

2 Q And as we discussed, Mr. Randall, bench testing should
3 predict as closely as possible what happens to the device in
4 the real world with living, breathing, human beings; right?

11:00:33 5 That should be a goal of bench testing, one of them; true?

6 A For bench testing. This -- this testing is comparing it
7 against other product that has been implanted.

8 Q I'm just talking about as a general principle, you and I
9 can agree today that a purpose of bench testing is to predict
11:00:59 10 how this filter will behave living, breathing human beings;
11 right?

12 A Yes.

13 Q And, sir, this testing did not simulate
14 endothelialization; true?

11:01:09 15 A True.

16 Q This test did not simulate perforation; correct?

17 A Correct.

18 Q This test did not simulate tilt; correct?

19 A Correct.

11:01:38 20 MR. O'CONNOR: And, Felice, if we can go back to
21 Exhibit 1222.

22 BY MR. O'CONNOR:

23 Q And, sir, I think you told us that this meeting was in
24 2008, actually. Does that sound about right?

11:01:58 25 A I believe it's around that time.

CROSS-EXAMINATION - MICHAEL RANDALL

11:02:00 1 Q And this dealt with the EVEREST study which dealt with the
2 G2; correct?

3 A We were -- Andrzej put together a presentation to review
4 EVEREST.

11:02:10 5 Q And EVEREST was the G2; correct?

6 A Yes.

7 Q We have to put everything in context in a timeline, Bard
8 was also talking about those days caudal anchors; true?

9 A I'm sorry, can you say that again?

11:02:23 10 Q If we took the timeline back to 2008 and go forward, Bard
11 was talking about caudal anchors back at this period of time;
12 correct?

13 A Yeah, trying to make an improvement there.

14 Q And in the EVEREST study, for however long it was, it was
11:02:37 15 a finite period and patients who had G2 filters experienced
16 complications within that period; true?

17 A Yes, there were reported complications in that study.

18 Q And what Bard knew -- if we go to page 8 --

19 MS. REED ZAIC: Publish, Counsel.

11:02:56 20 MR. O'CONNOR: Oh. May I publish?

21 THE COURT: Yes.

22 BY MR. O'CONNOR:

23 Q Number 1. "The greatest number of complications is
24 associated with penetrations, followed by tilts and caudal
11:03:06 25 migrations."

CROSS-EXAMINATION - MICHAEL RANDALL

11:03:07 1 Do you see where I read?

2 A Yes, I do.

3 Q And "There's a strong relationship between caudal
4 migrations and tilts." Do you see that?

11:03:21 5 A Yes, I do.

6 Q And we showed a chart Bard maintained earlier that showed
7 all its filters and all of the complications Bard was aware
8 of, presumably, as of July 2010. Do you recall that? Early
9 on, the chart I showed you.

11:03:32 10 A Oh, the color chart?

11 Q Yes. With the total complications. You recall that?

12 A I do remember you showing me, but that was the first time
13 I've seen that chart so I don't know exactly what that was.

14 Q That's fair.

11:03:44 15 MS. HELM: Excuse me, Your Honor.

16 MR. O'CONNOR: It's a Bard document.

17 THE COURT: Hold on.

18 MS. HELM: May Mr. Randall finish his answers before
19 Mr. O'Connor --

11:03:50 20 MR. O'CONNOR: Apologize --

21 THE COURT: Yes.

22 MR. O'CONNOR: -- I'm just trying to pick up the
23 pace.

24 I apologize, Mr. Randall.

11:03:54 25 THE WITNESS: I was just saying I hadn't seen that

CROSS-EXAMINATION - MICHAEL RANDALL

1 chart before so I don't know how that was put together or what
2 it's trying to say.

3 BY MR. O'CONNOR:

4 Q Here's the point: The G2, G2X, and the Eclipse, Bard
5 intended to put those and keep those on the market; right?

6 A Say that again.

7 Q It was Bard's intention to continue with the G2 on the
8 market even after the EVEREST study; correct?

9 A Even after the EVEREST study. Yes. The filter was on the
10 market after the EVEREST study, correct.

11 Q So it was an intentional plan by Bard; correct? Bard knew
12 and intended to keep it on the market.

13 A Yes. We used that study to gain retrievability and the
14 filter was on the market.

15 Q Understand that. But Bard intended to keep it on the
16 market knowing that it was failing in many different ways;
17 true?

18 A It was going to be kept on the market with those reported
19 complications.

20 Q Thank you.

21 So you had talked about unintended consequences. Can
22 we call that intended consequence?

23 A I'm sorry, say that again.

24 MS. HELM: Excuse me, Your Honor. I object.

25 MR. O'CONNOR: I'll withdraw the question.

REDIRECT EXAMINATION - MICHAEL RANDALL

11:05:13 1 THE COURT: All right.

2 MR. O'CONNOR: Thank you.

3 THE COURT: Redirect.

4 MS. HELM: Yes, Your Honor.

11:05:15 5 R E D I R E C T E X A M I N A T I O N

6 BY MS. HELM:

7 Q Mr. Randall, you were asked about some charts of adverse
8 events and comparison between Bard and other competitors. Do
9 you know how that document was prepared?

11:05:32 10 A No, I don't.

11 Q Do you know the source of the information in the document?

12 A No.

13 Q Do you know whether the data from the competitors reported
14 to MAUDE is at all the same as the data that Bard maintains
11:05:45 15 internally?

16 A No, I do not.

17 Q Do you know -- did Mr. O'Connor show you any sales numbers
18 for the competitors' filters compared to Bard's filters?

19 A No, he did not.

11:05:56 20 Q Did he show any rates for the competitors' filters
21 compared to Bard's filters?

22 A No.

23 Q Mr. Randall, as an engineer who spent your career at Bard
24 developing IVC filters, are you generally familiar with the
11:06:10 25 adverse events and the rates for the filters that you worked

REDIRECT EXAMINATION - MICHAEL RANDALL

1 on?

2 A Yes.

3 Q And how would you describe those rates?

4 A The rates of our filters are extremely low. Well below
5 one percent. The device performs very well.

6 Q And Mr. O'Connor also showed you a document that appeared
7 to be a page from an FDA website. Do you remember that?

8 A Yes.

9 Q Do you have any idea what the FDA was talking about on
10 that page?

11 A No.

12 Q Do you have any idea what the source of their information
13 was?

14 A No, I do not.

15 Q He also asked you a document about -- that said there was
16 a risk of the G2 platform, that it would need a clinical
17 trial. Do you recall that?

18 A Yes.

19 Q Can you put that in context for us. What do you mean you
20 were trying to develop the G2 Platinum without a clinical
21 trial?

22 A Yeah. So at this time there's numerous filter teams
23 working. I'm on the filter team where my goal is to try and
24 implement improvements right away. There's another team
25 working on improvements that's a completely brand new

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11:07:22 1 different design, which would take a clinical, but it's going
2 to be longer before we can implement and get it to the market.

3 So I'm trying to make improvements right away. That
4 is a risk that I have to do a clinical for my particular
11:07:36 5 project. For the other person's project, it's going to have a
6 clinical. So therefore it's not deemed a risk.

7 But I'm trying to implement changes sooner, so
8 there's only a certain amount of things you can do because
9 we're a heavily regulated industry. And their projects would
11:07:56 10 have an extended timeline and they have to do a clinical so
11 they don't show that as a risk.

12 So that's basically what it was showing.

13 Q He also asked you a question about the arm fatigue test
14 that we discussed with the G2X and the Eclipse. Do you recall
11:08:09 15 that?

16 A Yes.

17 Q And he said that the arm fatigue test did not evaluate
18 tilt or perforation. Do you recall those questions?

19 A Yes.

11:08:18 20 Q Was it the intent of the arm fatigue test to evaluate tilt
21 and perforation?

22 A No, it was not.

23 Q Were there other tests that Bard used to evaluate tilt and
24 perforation, such as animal studies or radial strength?

11:08:30 25 A Yes. That's where we would do the testing -- the only way

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11:08:33 1 to do endothelialization is something that's living. So you
2 have to put it in an animal. And that's where you get the
3 dynamics to see if it tilts and penetrates.

4 You can't replicate living tissue on the bench.

11:08:47 5 Q He also asked you about a couple of marketing documents
6 written by Bill Little and Bret Baird. Do you recall those?

7 A Yes.

8 Q And there was a delay. Did the FDA ask more questions
9 about the Meridian?

11:09:02 10 A Yes. We were going and back and forth. There was more
11 questions, more testing that needed to be performed. So it
12 delayed.

13 Q And during that time, Bard continued to sell the G2X and
14 the Eclipse filters; is that right? Or the G2 and the Eclipse
11:09:18 15 filters.

16 A Correct.

17 Q Did you agree with that decision?

18 A Yes.

19 Q Why?

11:09:25 20 A There were -- we were trying to get people to convert over
21 to Eclipse, but there's a lot of people who didn't want to go
22 over to Eclipse. They loved G2, they were perfectly happy
23 with G2 and didn't want to switch. So we were just trying to
24 provide the customers with the filters they wanted.

11:09:42 25 Q I want to talk to you very briefly about the Meridian and

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11:09:45 1 caudal anchors.

2 In the Meridian that was available as of August of
3 2011, Bard was able to successfully incorporate caudal
4 anchors; right?

11:09:57 5 A Correct.

6 Q And are you familiar -- have you followed -- did you
7 follow the Meridian while it was on the market and did you
8 receive reports of adverse events on the Meridian?

9 A Yes.

11:10:07 10 MR. O'CONNOR: Objection. Beyond my cross.

11 THE COURT: Overruled.

12 BY MS. HELM:

13 Q And, Mr. Randall, in following the reports of adverse
14 events, what did you see about the reports of adverse events
11:10:19 15 for caudal migration in the Meridian?

16 A I -- we reduced it almost down to zero. Very -- I mean
17 really close. We were successful in reducing that.

18 Q Were you able to successfully reduce tilt?

19 A We were able to reduce tilt, yes.

11:10:40 20 Q A lot, a little bit?

21 A A lot.

22 Q Were you able to reduce perforation?

23 A We were able to reduce perforation, too.

24 Q Were you able to reduce fracture?

11:10:53 25 A No, we weren't able to reduce fracture.

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11:10:59 1 Q Mr. Randall, do you have -- you've been asked multiple
2 times. Bard made the intentional decision to leave the G2X
3 and the Eclipse on the market even though you knew the
4 Meridian was coming down the road.

11:11:13 5 At any time did you ever feel that there was any
6 reason for Bard to remove the G2X -- the G2, the G2X, or the
7 Eclipse filters from the market?

8 A No.

9 Q Why?

11:11:25 10 A The complication profile for the filters was very low.
11 The benefits that it provide are lifesaving in terms of
12 trapping clot that can migrate to the heart and cause a
13 pulmonary embolism. So the benefits outweighed the risk in a,
14 you know, risk/benefit ratio analysis such as physicians would
11:11:46 15 have to conduct.

16 MS. HELM: Thank you, Your Honor. No further
17 questions.

18 THE COURT: Thank you, sir, you can step down.

19 MR. ROGERS: Your Honor, at this time the defense
11:11:57 20 rests.

21 THE COURT: All right.

22 Any further evidence from plaintiffs.

23 MR. O'CONNOR: Your Honor, pursuant to stipulation we
24 would offer to admit Exhibit 932.

11:12:58 25 MR. ROGERS: No objection, Your Honor.

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11:13:00 1 THE COURT: All right.

2 MR. O'CONNOR: Do you want me to describe the title
3 of it?

4 THE COURT: I think we've indicated the jury needs to
11:13:07 5 have some context for exhibits. You ought to talk about what
6 you agree the context is.

7 MR. O'CONNOR: Just the title?

8 MR. ROGERS: Yeah, I think the title is fine and
9 certain witnesses have testified about it. I think that would
11:13:20 10 get it done.

11 MR. O'CONNOR: Your Honor, the title of the document
12 is Bard Peripheral Vascular Filter Franchise Review. It's
13 dated May 6, 2008. And there has been testimony, I think,
14 from a number of witnesses on this document.

11:13:35 15 THE COURT: All right. That document is admitted.
16 (Exhibit 932 admitted.)

17 THE COURT: Anything further from plaintiffs?

18 MR. O'CONNOR: Nothing further from us, thank you.

19 THE COURT: All right. So plaintiffs rest?

11:13:48 20 MR. O'CONNOR: Yes, Your Honor.

21 THE COURT: All right.

22 Ladies and gentlemen, we've reached the end of the
23 evidence.

24 The next step is for me to give you jury
11:13:55 25 instructions. Before I do that, however, I need to resolve a

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11:13:59 1 legal issue with the parties. That will take me ten minutes
2 or so. So what we will do is take another break, we know you
3 just had one. We'll get that legal issue resolved so I can
4 then give you the jury instructions before we break for lunch,
11:14:12 5 then we'll take our lunch break and afterward we'll hear
6 closing arguments from the parties.

7 Please remember not to discuss the case yet and we'll
8 excuse you and get you back in here just as soon as we resolve
9 this legal issue.

11:14:26 10 (The jury exited the courtroom at 11:14.)

11 THE COURT: All right. Counsel, in terms of time,
12 plaintiffs have used 32 hours and 31 minutes. So you have 1
13 hour and 19 minutes for closing argument and punitives.

14 Defendants have used 27 hours and 15 minutes, which
11:15:24 15 means you retain 2 hours and 45 minutes for closing arguments
16 and punitives.

17 All right. Rule 50 motion?

18 MR. GOLDENBERG: Thank you, Your Honor.

19 We've already made our objection on the law to the
11:15:37 20 insertion of the inherent characteristic instruction, so that
21 not need be repeated. But we now would like --

22 THE COURT: Pardon me. Let me interrupt you for just
23 a minute. Sorry.

24 Traci, I left my copy of the jury instructions on my
11:15:52 25 desk. Oh, Jeff has a copy. But I want the one with the tabs.

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11:15:52 1 It's got yellow tabs.

2 MR. ROGERS: Your Honor, I've got extra --

3 THE COURT: I want the one with tabs on it. I just
4 want to call out a couple of things when we're done.

11:16:04 5 Sorry to interrupt. Go ahead.

6 MR. GOLDENBERG: Of course, Your Honor. If you don't
7 mine, I'll just start over if that's okay.

8 THE COURT: Please.

9 MR. GOLDENBERG: We've already made our objection on
11:16:13 10 the law to the insertion of the inherent characteristic
11 instruction, so that not need be repeated to you. But we're
12 now making a Rule 59(a) motion that a reasonable jury would
13 not have a legally sufficient evidentiary basis to find for
14 the defendant in this issue.

11:16:30 15 The instruction reads "The plaintiffs may not recover
16 on their strict liability claim if the damage was caused by an
17 inherent characteristic of the product that would be
18 recognized by an ordinary person with ordinary knowledge
19 common to the community that uses or consumes the product."

11:16:47 20 I'd like to focus more on the "ordinary person" part
21 of this and the evidence that's been presented.

22 The G2X and the Eclipse are not like a sharp knife
23 where an ordinary consumer can appreciate and understand the
24 danger of the sharpness. We assume Bard will argue that an
11:17:05 25 inherent characteristic of all filters is fracture and

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11:17:12 1 everybody knows about it. However, in fact an inherent
2 characteristic means Bard could do nothing about it or prevent
3 it, like an ingredient or process which can't be eliminated or
4 minimized.

11:17:25 5 If you look up the word "inherent," it stands for
6 qualities are that permanent, essential, and cannot be change
7 changed. There's been no evidence presented that an ordinary
8 person like the plaintiff or even her doctor had the ability
9 or knowledge to recognize, understand, or appreciate that Bard
11:17:42 10 retrievable filters have an inherent characteristic to
11 fracture into the heart and these filters in 2011 could not be
12 made to minimize the risk of fracture into the heart.

13 The ordinary consumer in this case is Ms. Hyde or
14 possibly Dr. Henry. Even though we don't necessarily agree
11:18:01 15 with that definition, I'm sure it will be argued.

16 The only evidence presented in this case on what
17 Ms. Hyde knew about this inherent characteristic is as
18 follows:

19 Ms. Hyde testified on page 1680 of her transcript as
11:18:15 20 follows:

21 "Do you have any reason to believe or expect that the
22 Bard filter inside of you would penetrate through the walls of
23 the vena cava?"

24 "No."

11:18:23 25 "Do you have any reason to ever think that the legs

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1 of the filter would perforate through and penetrate your
2 aorta?"

3 "No."

4 "Did you ever think or become concerned that the
5 filter could go through and actually penetrate to your
6 vertebrae and into your back?"

7 "Not at all."

8 "Did you ever expect or have any reason to expect
9 that the filter that you thought was going to help you would
10 break and land a piece in your right ventricle of your heart?"

11 "No."

12 The defense may attempt to argue, Your Honor, that
13 Dr. Henry, the implanting doctor, is somehow an ordinary
14 consumer even though there's been no case law that presented
15 on that that finds a doctor as an ordinary consumer.

16 What does the evidence show that Dr. Henry expected
17 in this case about whether a filter would fracture into
18 Mrs. Hyde's heart?

19 Starting on 84, line 20, of his transcript it states,
20 "Question: At the time you implanted the filter, you expected
21 it to remain affixed in the proper location in the IVC?" .

22 "Answer: Yes."

23 "Question: You expected it would remain intact and
24 not fracture?"

25 "Answer: Yes."

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1 The defendant may attempt to argue in this situation
2 they put a mention of the filter fracture in the IFUs.
3 However, just because filter fracture is mentioned in the IFUs
4 does not mean they've presented evidence that an ordinary
5 consumer with common knowledge would know that an inherent
6 feature, a feature that cannot be changed of the filter, was
7 that it fractures into the heart and, like the sharpness of a
8 knife, there's nothing they could do about it. There's no
9 warning to anyone about this being an inherent characteristic
10 that cannot be reduced or eliminated.

11 Additionally, the retrievability of the filter is not
12 an inherent characteristic since all retrievable filters are
13 also intended to be permanent. There's been no evidence
14 presented by Bard in this case that an ordinary consumer and
15 doctor knew and appreciated that a temporary filter could not
16 and should not perform as safely as a permanent filter.

17 A reasonable jury would not have a sufficient -- a
18 legal sufficient evidentiary basis to find for the party in
19 this issue. And the Court, we ask, would resolve this issue
20 against the defendant and grant a motion for summary judgment
21 as a matter of law against the defendant on this issue. Thank
22 you.

23 THE COURT: All right. Thank you.

24 MR. NORTH: Your Honor, if the ordinary consumer was
25 indeed the plaintiff herself under the statute we believe the

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11:21:03 1 plaintiff might have a viable argument. However, the
2 statutory language itself, I believe, suggests that it's got
3 to be, in this context, the physician.

4 The statutory language regarding the inherent
11:21:22 5 characteristic defense talks about that would be recognized by
6 an ordinary person with ordinary knowledge common to the
7 community that uses or consumes the product.

8 In this particular case, the community that uses the
9 product are interventional radiologists.

11:21:40 10 Mr. Goldenberg is correct, there are no authorities
11 on these cases, actually, beyond the statutory language
12 itself. But there is the *Hall* case in West Virginia. And,
13 tellingly, there the court didn't even have to address the
14 issue of defining the ordinary consumer because, as Judge
11:22:00 15 Goodwin in that case indicated in a footnote, the parties
16 agreed the ordinary consumer for the medical device, the mesh
17 product there, was the physicians that used and implanted the
18 product.

19 Your Honor, we believe the plain language of the
11:22:14 20 statute under these circumstances indicates that it would
21 apply, as far as the ordinary person, being the doctor in this
22 case.

23 As far as the record goes, we believe there is ample
24 evidence at least to present a question of fact to this jury
11:22:32 25 as to whether the propensity or ability of filters to fracture

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11:22:37 1 is indeed an inherent characteristic of all such products.

2 Multiple, multiple experts on both sides, plaintiffs
3 and defendants, have testified repeatedly that all filters
4 fracture, all filters migrate, all filters tilt, all filters
11:22:57 5 penetrate. That provides a question of fact to this jury, we
6 believe, as to whether that is an inherent characteristic.

7 Now, Mr. Goldenberg and his team may have some good
8 arguments to the jury, perhaps, on that question of fact.
9 Arguments that, well, we don't believe it is an inherent
11:23:18 10 characteristic or we believe Bard's filters have complications
11 at higher rates than competitive filters, but those are jury
12 arguments. They're not a resolution of this issue as a matter
13 of law.

14 The fact of the matter is we have presented evidence
11:23:33 15 that would allow this jury to conclude that the capability of
16 filters to fracture is an inherent characteristic of the
17 product and it is known to ordinary persons common to the
18 community that uses or consumes the product, i.e., the
19 interventional radiologist. And on that basis, Your Honor, we
11:23:55 20 would ask that the motion be denied.

21 MR. GOLDENBERG: Your Honor, I would only say, again,
22 Mr. North made the exact argument I would have anticipated he
23 would make, but he did not address what the definition of
24 "inherent" is.

11:24:17 25 And permanent and something that cannot be changed is

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11:24:23 1 what the definition of "inherent characteristic" is. There's
2 been no evidence in this case that Bard told anybody that this
3 was an inherent characteristic of the product, could not be
4 changed, could not be eliminated, and that it would fracture
11:24:40 5 into their heart. So we stand by what we said before.

6 Thank you.

7 THE COURT: Okay. Thank you.

8 Somebody has their phone on, by the way. Oh, and let
9 me mention this. Nancy might have mentioned it. At some
11:25:14 10 point there's going to be a national alert that will hit every
11 phone. So please make sure your phones are off.

12 Pardon?

13 MR. STOLLER: It's supposed to have happened already.

14 THE COURT: That's good. Thank you. We still need
11:25:27 15 phones off.

16 The question I need to answer on the Rule 50 motion
17 is whether evidence has been presented from which a reasonable
18 jury could find that Mrs. Hyde's damages were caused by an
19 inherent characteristic of the filter that would be recognized
11:25:54 20 by an ordinary person with ordinary knowledge common to the
21 community that uses or consumes the product.

22 Defendants have presented evidence that fracture and
23 migration of filter fragments is a characteristic inherent to
24 all filters, that it happens with all filters.

11:26:22 25 There's a dispute as to whether it happened with Bard

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11:26:25 1 filters more than other filters, but certainly defendants have
2 presented evidence that fracture and embolization happens with
3 all filters.

4 From that evidence the jury could conclude, I don't
11:26:38 5 know if they will, but they could conclude that fracture of
6 filters and embolization of a strut are inherent
7 characteristics of all filters.

8 Bard has also presented evidence that doctors --
9 well, assuming a doctor is -- doctors are the community that
11:27:01 10 uses or consumes the product, which I think a jury could
11 conclude because certainly interventional radiologists are
12 such a community, Bard has presented evidence that doctors in
13 that community understand that filters fracture and embolize.
14 Therefore, a jury could conclude on the basis of the evidence
11:27:24 15 that fracture and embolization is an inherent characteristic
16 of the filter that would be recognized by an ordinary
17 interventional radiologist. I don't know if the jury's going
18 to come out that way. But I think there's evidence from which
19 they could and therefore I'm going to deny the Rule 50 motion.

11:27:45 20 Let me mention some very minor word changes, Counsel,
21 that we made in these instructions just so you're aware of
22 them.

23 As we gave them to you last night, instruction number
24 11 referred to Mrs. Hyde's first claim as strict liability
11:28:15 25 based on design defect. It still does. But instruction

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11:28:21 1 number 13 didn't mention strict liability. And so the jury
2 could connect those two, I changed the second sentence in
3 instruction 13 to say "To prove liability of Bard for the
4 strict liability design defect claim." It had previously just
11:28:40 5 said "the design defect claim." So we put "strict liability"
6 in there to make it clear to the jury.

7 And we also changed the language in the verdict form
8 on the first claim from "strict product liability design
9 defect" to "strict liability design defect" so it's the same
11:29:00 10 language as these two instructions.

11 Instruction number 14 that you have in front of you
12 is slightly different from what Bard proposed in that we said
13 "Mrs. Hyde" rather than "plaintiff" may not recover. So we
14 just replaced "plaintiff" with "Mrs. Hyde."

11:29:42 15 And otherwise we track the wording of the statute
16 exactly.

17 Jeff, were there other minor wording changes we made?
18 Those are the two I remember.

19 LAW CLERK: I think that's it.

11:29:59 20 THE COURT: Everything else is the way that we
21 previously -- that I had previously ruled.

22 Anything else we need to address before we bring the
23 jury in for instructions?

24 MR. ROGERS: I have one thing, Your Honor.

11:30:10 25 THE COURT: Yes.

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11:30:10 1 MR. ROGERS: For purposes of the record, Your Honor,
2 I would like to renew the Rule 50 motions that Bard made
3 previously that the Court has denied. And I would also like
4 to add one thing to the Rule 50 motion at this time. And that
11:30:25 5 would be a Rule 50 that there is no evidence of any past
6 medical expenses that have been introduced in this case.

7 The only evidence of any actual medical expenses are
8 all future medical expenses. And, Your Honor, I'll point out
9 that in instruction number 17, in the last paragraph, it does
11:30:50 10 indicate "Personal injuries can also include healthcare and
11 treatment expenses both past and future." And it goes on to
12 say that "You should award Mrs. Hyde the sum of money you find
13 has reasonably and necessarily been incurred up to this time
14 for the care and injuries," et cetera.

11:31:13 15 So, Your Honor, plaintiffs did not introduce any
16 evidence of any past medical expenses.

17 MR. GOLDENBERG: Your Honor, we did not introduce any
18 medical expenses. However, it is -- if you look at the way
19 this instruction is written, personal injuries can include
11:31:42 20 healthcare and treatment and expenses. It doesn't say they
21 must. And it says you should award Ms. Hyde the sum of money
22 you find has reasonably and necessarily been incurred up to
23 the time for care of injuries sustained by her. So I think
24 that really comes down to your decision. But we believe the
11:31:58 25 instruction should stand as written.

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11:32:04 1 THE COURT: All right. Let's talk about the
2 instruction in a minute.

3 Rule 50, as you know, can be on an issue. It doesn't
4 have to be on a defense or claim. It sounds as though there's
11:32:14 5 no disagreement from plaintiffs that I should grant the
6 Rule 50 motion on the issue of past medical expenses. Is that
7 correct?

8 MR. GOLDENBERG: To make sure that we put this on the
9 record, there was evidence in testimony that she did go to the
11:32:46 10 hospital, she did have treatment. The fact that the medical
11 expenses were not put in doesn't necessarily preclude us from
12 recovering. It's up to the jury if they find that there was
13 reasonable testimony and evidence that provides them with
14 enough to be able to assess damages in this case.

11:33:07 15 THE COURT: Well, let me ask a question on that.

16 MR. GOLDENBERG: Your Honor, I'd add one other thing.
17 Jurors are allowed to make reasonable inferences as well, and
18 from the future care they could absolutely infer what the past
19 care could be.

11:33:48 20 THE COURT: Well, I think -- I think the right way to
21 frame the question is to ask whether the jury has received
22 evidence from which they reasonably could make an award of
23 past medical expenses. If the answer is yes, I deny the
24 motion; if the answer is no, I grant the motion.

11:34:22 25 And your argument is that a jury reasonably could

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11:34:25 1 say, well, we know she incurred past expenses, we have a sense
2 for what they're going to cost in the future, so we'll
3 approximate what they've been in the past and could award
4 them. That's the argument; right?

11:34:40 5 MR. GOLDENBERG: That's the argument, Your Honor.
6 reasonable inference.

7 MR. ROGERS: Your Honor, I think that that completely
8 invites the jury to completely speculate with no basis
9 whatsoever.

11:34:48 10 The plaintiffs had a bill from Stanford for \$10,000
11 that I'm assuming they elected not to put in. And they're
12 going to put in a future claim for \$227,000. And the jury has
13 heard that Mrs. Hyde did go to a cardiologist. They heard she
14 traveled to Stanford. Without any guidance about what these
11:35:11 15 medical expenses would cost, I think it's just up to the wild
16 imagination of the jurors as to what those could be. And I
17 think that is highly prejudicial to the defendants to ask the
18 jurors to infer and speculate about what these medical
19 expenses would be in a complete vacuum as far as any real
11:35:30 20 information about what those costs were.

21 MR. GOLDENBERG: Your Honor, could you give me just
22 one minute to go grab the jury instructions. I believe that
23 there's a case on point on this, if I could just go grab them.

24 THE COURT: Yes.

11:36:17 25 Counsel, I think I just discovered a mistake in the

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11:36:21 1 instructions. It's a very minor one but we ought to fix it.

2 In instruction number 17 where I'm talking about --
3 in the second paragraph where I'm talking about the burden of
4 proof, the last sentence says, "As you have seen, instruction
11:36:36 5 13 provides a further explanation."

6 That's now instruction 12.

7 MR. ROGERS: I'm sorry, Your Honor, what is the
8 instruction number?

9 THE COURT: Instruction 17. End of the second
11:36:49 10 paragraph we refer them back to instruction 13, but that has
11 become instruction 12. So we'll make that correction.

12 MR. GOLDENBERG: Your Honor, do you have the
13 reference to instruction 17 in the Wisconsin jig?

14 THE COURT: I do on my desk. You mean which specific
11:37:20 15 instruction it is?

16 MR. GOLDENBERG: I just need the number because the
17 annotations have the cases in them.

18 THE COURT: It's in the book at the back. Yeah,
19 we've got it.

11:37:33 20 MR. GOLDENBERG: Oh, I have it right here. Just a
21 minute.

22 1756. Just one second.

23 THE COURT: 1756 and 1766 from which I got in the
24 instructions.

11:38:47 25 MR. GOLDENBERG: I think there's some helpful cases,

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11:38:49 1 Your Honor, that are in the comments on -- I guess it would be
2 page 2 of Wisconsin JI civil 1756 that just talk about what
3 the definitions are of proper measure of damages. And it says
4 while -- "While the actual amount paid for services may
11:39:10 5 reflect the reasonable value of the treatment rendered, the
6 focus is on the reasonable value not the actual charge."

7 So the jury determines the reasonable value of the
8 treatment, which is not necessarily the amount actually paid
9 or the amount billed for the treatment. And the name of the
11:39:27 10 case is *Leitinger*, L-E-I-T-I-N-G-E-R, *versus* *DBart*, and that's
11 302 Wisconsin 2d 110 or 736 Northwest 2d 1.

12 And I think that's the case that we'd be referring
13 to.

14 THE COURT: The *Leitinger* case that's been discussed
11:43:24 15 I just pulled up and I've been reviewing it.

16 It's a statement of the law. It doesn't seem to
17 address the exact proof required. After the statement of law
18 it goes on to discuss the collateral source rule.

19 But it says, I'm now reading from paragraph 23, "The
11:43:44 20 proper measure of damages for medical treatment rendered in a
21 personal injury action, is a -- is the reasonable value of the
22 medical treatment reasonably required by the injury.

23 The court has explained that while the actual amount
24 paid for medical services may reflect the reasonable value of
11:44:04 25 the treatment rendered, the focus is on the reasonable value,

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11:44:08 1 not the actual charge.

2 In other words, this is a recovery for their value
3 and not for the expenditures actually made or obligations
4 incurred.

11:44:19 5 The value of medical services made necessary by the
6 tort can ordinarily be recovered although they have created no
7 liability or expense to the injured person.

8 Then cites a number of cases.

9 And then it says, "Thus, the fact finder determines
11:44:36 10 the reasonable value of the medical treatment rendered which
11 is not necessarily the amount actually paid or the amount
12 billed for the treatment."

13 And then the footnote to that just cites more cases
14 and it goes directly into a discussion of the collateral
11:44:57 15 source rule in the next section.

16 I understand plaintiffs' arguments in light of that.

17 Mr. Rogers, did you want to address that?

18 MR. ROGERS: Your Honor, I will add in the charge
19 that comes after the one we were just discussing that has the
11:45:14 20 *Leitinger* case, there is a Wisconsin statute that was passed
21 looks like in 2009 that is a statutory adoption of what the
22 collateral source rule is in Wisconsin. And that statute
23 contains a provision that says "Billing statements or invoices
24 that are patient healthcare records are presumed to state the
11:45:40 25 reasonable value of the healthcare services provided, and the

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1 healthcare services provided are presumed to be reasonable
2 necessary to the care of the patient.

3 "Any party attempting to rebut the presumption of the
4 reasonable value of the healthcare services provided may not
5 present evidence of payments made or benefits conferred by
6 collateral sources.

7 So, Your Honor, I think that's further indication
8 that this is teeing off of the need for evidence that would
9 establish what the reasonable value is and in this case there
10 is no evidence at all of what these damages are.

11 And I think it's also important to consider yeah,
12 plaintiffs' counsel had the invoice and did not introduce it
13 in their case. And Mr. O'Connor asked us if we would
14 stipulate to admissibility of that invoice and we said yes.

15 And they have made a conscious election not to
16 introduce that invoice for \$10,000. And I think would like
17 the jury to speculate that a trip to Stanford, to a world
18 renowned institution to have this procedure done, is much more
19 than the actual evidence that could have been introduced. And
20 I think that is highly prejudicial to Bard and unfair.

21 THE COURT: Response to that.

22 MR. GOLDENBERG: My response, Your Honor, is that
23 this presumption of reasonable value is everything to do with
24 collateral source and nothing to do with the proof of the
25 bills. I think the *Leitinger* case is the most reflective of

REDIRECT EXAMINATION - MICHAEL RANDALL

11:47:19 1 that. Again, reasonable value is what the jury believes
2 reasonable value is according to the state, according to the
3 case law.

4 THE COURT: My memory of the evidence that's been
11:47:30 5 introduced on future medical expenses, \$200,000 plus, that was
6 that consists of the cost of an annual visit to a
7 cardiologist, an EKG, an echocardiogram for the anticipated
8 remaining life of Mrs. Hyde. Am I right about that? Does it
9 include anything else?

11:48:05 10 MR. ROGERS: No.

11 MR. GOLDENBERG: That's correct.

12 MR. ROGERS: I believe the jury also heard evidence
13 of the future cost of the defibrillator.

14 THE COURT: Right, but with dealt with that in the
11:48:15 15 instructions.

16 MR. ROGERS: I understand. But the point I wanted to
17 make was the future cost of that was \$166,000. So the jury's
18 heard that.

19 THE COURT: Right.

11:48:25 20 MR. ROGERS: So they've heard evidence about a
21 procedure.

22 THE COURT: But am I right about the future cost?

23 MR. GOLDENBERG: You are, Your Honor.

24 THE COURT: Here's the question that creates for me.
11:48:36 25 The evidence they can consider on future damages concerns

REDIRECT EXAMINATION - MICHAEL RANDALL

11:48:41 1 medical monitoring.

2 MR. GOLDENBERG: Concerns what?

3 THE COURT: Medical monitoring. Cardiac monitoring.

4 I think Mrs. Hyde has testified she has not had
11:48:51 5 cardiac monitoring since the filter was removed. At least not
6 annual cardiac monitoring.

7 How does the annual future cost of cardiac monitoring
8 provide a basis from which the jury can reasonably infer the
9 amount of her past expenses if it hasn't included annual
11:49:12 10 cardiac monitoring?

11 MR. GOLDENBERG: I think, Your Honor, that's not
12 necessary under the *Leitinger* case. I mean, medical bills
13 don't necessarily reflect the value of the medical services.
14 That's basically what it says.

11:49:25 15 So I think that they can look at those, they can use
16 their common sense. People have had a lot of medical care
17 over the years. I mean, I think that the *Leitinger* case says
18 exactly what it says and they can also look to that as
19 something to help them infer what these costs might be.

11:49:49 20 THE COURT: The only thing, though, that you've
21 pointed to for the inference are those future medical
22 monitoring costs, right, in terms of what's in the evidence.

23 MR. GOLDENBERG: Well, there was testimony about what
24 they did, Your Honor. What they did, where they went, how
11:50:10 25 they did it. I think those are all things that are worthy of

REDIRECT EXAMINATION - MICHAEL RANDALL

11:50:14 1 consideration.

2 THE COURT: In the instruction on the burden of proof
3 for the plaintiffs, number 12, I tell them that "It's the
4 plaintiffs' burden" -- I'm now reading in the second sentence
11:50:33 5 of the second paragraph -- "to satisfy you by the greater
6 weight of the credible evidence to a reasonable certainty that
7 you should find for the plaintiffs."

8 And then down at the bottom, I define "reasonable
9 certainty" to mean "That you are persuaded based upon a
11:50:51 10 rational consideration of the evidence. Absolute certainty is
11 not required, but a guess is not enough to meet the burden of
12 proof."

13 So for purposes of deciding the reasonable certainty,
14 I think I need to decide whether or not the future medical
11:51:11 15 monitoring cost evidence that has been presented and the
16 description of Mrs. Hyde's past medical activities provides a
17 sufficient basis for a jury to arrive at the value of past
18 medical expenses to a reasonable certainty.

19 In other words, they can't guess.

11:51:40 20 That's, I think, the question. Do you both agree
21 that's the question?

22 MR. GOLDENBERG: I do.

23 MR. ROGERS: Yes, Your Honor.

24 THE COURT: *Leitinger* says it's the value not the
11:51:51 25 amount.

REDIRECT EXAMINATION - MICHAEL RANDALL

11:51:51 1 I agree with you, by the way, the statute I don't
2 think is helpful. It's creating the opposite presumption: If
3 the medical records are in, they're presumed to be reasonable
4 value unless rebutted. It doesn't say what you do if there
11:52:05 5 are no medical records.

6 *Leitinger* says that the jury must determine the value
7 and isn't bound by actual expenses.

8 It doesn't say anything about what evidence is needed
9 for a jury to arrive in an actual value and it doesn't say
11:52:23 10 that a jury can simply rely on its common sense to do so.
11 There needs to be evidence of it.

12 I wish we had more time to brief this so we could
13 look at more cases.

14 My reaction to this is that future medical monitoring
11:52:45 15 costs plus a past description of events does not give the jury
16 a reasonable basis to find the cost of those past events to a
17 reasonable certainty.

18 The past events were not medical monitoring. There's
19 been no evidence about the cost of those events.

11:53:03 20 And I don't think I can deny a Rule 50 motion simply
21 by saying, "Each of you think about how much you've paid for
22 medical expenses." That's not evidence in the case. The
23 verdict can't be based on that.

24 So in the absence of more definitive case law at this
11:53:20 25 five-minutes-to-noon discussion, I'm having difficulty seeing

REDIRECT EXAMINATION - MICHAEL RANDALL

11:53:30 1 how they have enough evidence.

2 But since we're at five minutes to noon I think what
3 I'm going to do is this: I think I'm going to bring the jury
4 back in, apologize to them, and break for lunch. We'll then
11:53:41 5 resume at 1 o'clock.

6 That will give me some time to look for additional
7 case law that might bear light on this issue. So I'll do
8 that.

9 MR. GOLDENBERG: Thank you, Your Honor.

11:53:51 10 (The jury entered the courtroom at 11:54.)

11 THE COURT: Please be seated.

12 I'm sorry. That wasn't ten minutes. That was 35, 36
13 minutes.

14 And after our long discussion I decided I need to
11:55:36 15 read a few cases. So we're going to break for lunch and I'll
16 give you instructions after lunch. I'm sorry to do that, but
17 this is a legal issue I need to decide to know exactly what
18 should be in your instructions. So I can't instruct you until
19 I resolve it. And so I need to read a few cases. I don't
11:55:53 20 want to keep you in there waiting while I do that and then
21 bring you back in and send you to lunch.

22 So we'll take our regular lunch break even though
23 you've been cooling your heels for 35 minutes. And we will
24 plan to start at 1 o'clock. By that time I'll be prepared to
11:56:10 25 give you the instructions and then we'll go directly into

11:56:11 1 closing arguments.

2 Please remember not to discuss the case or do any
3 research.

4 We'll excuse the jury at this time.

11:56:16 5 (The jury exited the courtroom.)

6 THE COURT: All right. Counsel, we'll -- what I'm
7 going to do, by the way, is read the cases that follow the
8 *Leitinger* cite in that comment. Those seem to be the cases
9 the crafters of the jury instruction think are relevant.

11:56:50 10 We'll see if they shed any light on it.

11 If you could be back here five minutes to 1:00, I'll
12 be able to tell you my decision.

13 If you want to bring the lectern out for purposes of
14 your closing, let's get that done during the lunch break as
11:57:01 15 well. Thank you.

16 (End of a.m. session transcript.)

17 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 4th day of October, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter